CCPCVMGase 1:08-cv-03280-GBPEMEDQCUMENT 9 STAFILED 04/18/2008 RK Page 101/16/2008

INDEX NO: 106237 2005 E NEW YORK COUNTY CLERK TIME: 11:14:07
PURCHASE: 05042005 CIVIL INDEX MINUTE BOOK INQUIRY

PLAINTIFF NAME: BILIK HELEN DEFENDANT NAME: PFIZER INC

ATTORNEY: RONALD R. BENJAMIN ATTORNEY: UNKNOWN
126 RIVERSIDE DRIVE

BINGHAMTON, NEW YOR

1-607 772-1442 MINUTES

0001 05042005 SUMMONS AND COMPLAINT

0001 05262005 ACKNOWLEDGEMENT OF RECEIPT

0001 06152005 ANSWER

SEQ DATE

INTERROGATORIES

0001 07142005 LETTER

NEXT INDEX NUMBER:

F2=PRINT F3=EXIT F5=VIEW NEXT F7=BACKWARD F8=FORWARD F12=EXIT MAIN

CCPCVMGase 1:08-cv-032805GBREMEDOGUMENt9STAFiled 04/18/2008RK Page 26 101/16/2008 INDEX NO: 106237 2005 E NEW YORK COUNTY CLERK TIME: 11:14:07
PURCHASE: 05042005 CIVIL INDEX MINUTE BOOK INQUIRY

PLAINTIFF NAME: BILIK HELEN

ATTORNEY: BILIK HELEN DEFENDANT NAME: PFIZER INC
ATTORNEY: RONALD R. BENJAMIN ATTORNEY: UNKNOWN
126 RIVERSIDE DRIVE
BINGHAMTON NEW TORNEY: UNKNOWN

1-607 772-1442

SEQ DATE 0001 02102006 SHORT FORM ORDER IAS PART 39 SEQ 01

MINUTES

0001 03022006 ORDER IAS PART 54 SEQ 001 WITHDRAWN

0001 11142006 1NTERROGATORIES

0001 03062008 PARTIAL DISMISSAL STIPULATION WITH PRE-

JUDICE AGAINST PFIZER DEFENDANTS

NEXT INDEX NUMBER:

F2=PRINT F3=EXIT F5=V1EW NEXT F7=BACKWARD F8=FORWARD F12=EXIT MAIN

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS.

Plaintiffs,

-against-

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a whollyowned subsidiary of PHARMACIA CORPORATION, and MERCK & CO., INC.,

Defendants.

TO THE ABOVE NAMED DEFENDANT(S):

05106237

SUMMONS

Plaintiff designates New York County as place of trial based on defendants' principal place of business Index No.: Date Filed:

MAY 0 4 2005

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's undersigned attorney within twenty (20) days after service of this summons, exclusive of the day of service (or within thirty (30) days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: April 28, 2005

Binghamton, New York

Plaintiffs' residences are:

Helen Bilik, 38 Carol Court, Endwell, New York 13760 Elizabeth Boone, 12 Varick Street, Binghamton, New York 13905 Mary J. Mahar, 2803 Country Club Road, Endwell, New York 13760 Carolyn Croft, 512 Reynolds Road, Apt. D22, Johnson City, New York 13790 Geraldine M. Alapeck, 4 Holland Avenue, Binghamton, New York 13905 Dean Santacrose, 606 Wilson Avenue, Endwell, New York 13760 Stasia Simmons, 20 Cary Street, Binghamton, New York 13901

Defendants' Addresses:

Pfizer Inc., 245 E. 42nd Street, New York, NY 10017-5755

Pharmacia Corporation, 100 Route 203, North Peapack, NJ 07977

Pharmacia & Upjohn Company, Tax Dept., 88-106, 7000 Portage Road, Kalamazoo, MI 49001

Merck & Co., Inc., One Merck Drive, P.O. Box 100 WS3AB-05, Whitehouse Station, NJ 08889-0100

Ronald R. Benjamin, Esq.

LAW OFFICES OF RONALD R. BENJAMIN

Attorney for Plaintiff

126 Riverside Drive

P.O. Box 607

Biughamton, New York 13902-0607

(607) 772-1442

STATE OF NEW YORK:	SUPREME	COURT
COUNTY OF NEW YORE	ζ.	

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN'S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS,

COMPLAINT

Date Filed:

Plaintiffs,

-vs- Index No. :

PFIZER, INC., PHARMACIA CORPORATION, a whollyown subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO, INC,

Plaintiffs HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS, by and through counsel, the Law Office of Ronald R. Benjamin, complaining of each defendant, allege as follows:

- 1. Plaintiffs are and at all times relevant herein were residents of and domiciled in the State of New York.
- 2. Upon information and belief, defendant PFIZER INC., is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York, and is authorized to do and doing business in the State of New York with the county of its principal office registered as New York County.
- 3. Upon information and belief, defendant PHARMACIA & UPJOHN COMPANY is a wholly-owned subsidiary of PHARMACIA CORPORATION, and at times relevant to this

complaint, each was a foreign corporation incorporated in the State of Delaware, and authorized to do business in the State of New York, registered in or with its principal office located in New York County.

- 4. Upon information and belief, as the result of a corporate merger between Pfizer, Inc., and Pharmacia Corporation in or about April 2004, Pharmacia Corporation which is a wholly-owned subsidiary of Pfizer, Inc., and, as a result thereof, Pfizer, Inc., is legally responsible for all obligations, debts and liabilities of Pharmacia Corporation and Pharmacia & Upjohn Company, and is the successor in interest and real party to Pharmacia Corporation and Pharmacia & Upjohn Company (hereafter collectively referred to as "Pfizer defendants").
- 5. Upon information and belief, at all times relevant hereto defendant MERCK & CO. INC. (hereafter "Merck" or defendant), was and is a foreign corporation by virtue of being incorporated in New Jersey, and has its principal place of business at One Merck Drive, P.O. Box 100, WS3AB-05 Whitehouse Station, New Jersey 08889-01000, and is authorized to do business in the State of New York, with its registered principal office located at 111 Eightlı Avenue, New York, NY 10011, in the County of New York.
- 6. At all relevant times herein mentioned the Pfizer defendants engaged in manufacture, design, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of their respective pharmaceutical products including the non-steroidal anti-inflammatory arthritis and acute pain medications CELEBREX (celecoxib) and BEXTRA (valdecoxib), which are selective inhibitors of cyclo-oxygenase 2 (COX-2), for ultimate sale and/or use in the United States of America as well as in countries throughout the world.
- 7. At all relevant times herein mentioned the defendant Merck engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, pronotion, and/or distribution of pharmaceutical products including the non-

steroidal anti-inflammatory arthritis and acute pain medication VIOXX (rofecoxib), a selective COX-2 inhibitor, for ultimate sale and/or use in the United States of America as well as in countries throughout the world.

- 8. Each of the defendants are liable for the acts and transactions complained of herein that occurred and injured plaintiffs in and thus had consequences in the State of New York.
- 9. Upon information and belief, each of the defendants used a wide range of marketing methods to promote the aforesaid products and place the same in the stream of commerce, including, but not limited to, sponsoring medical journals to promote the alleged benefits of their products, using sales representatives including detailmen to call to on physicians throughout the country to encourage them to prescribe each of the defendants' products, sponsoring continued medical education programs for the express purpose of promoting their products, hiring experts in the field to speak to physicians for purposes of promoting their products, by direct advertisements to consumers and end- users of the products, and by utilizing the media to promote the alleged benefits of the products.
- 10. Upon information and belief, each of the defendants engaged in extensive advertising and promotional activity which indicated their drugs were efficacious for treating and safe to use, and published a description of their respective drugs in the Physician's Desk Reference for use by doctors in determining whether to prescribe said drugs to patients, including plaintiffs.
- 11. Upon information and belief, due to defendant's promotional activity with respect to the aforesaid products, each of the plaintiffs were prescribed the drugs based on the belief the same were safe to use and unlikely to subject each injured plaintiff to serious side effects as a result of use of the products.
- 12. Upon information and belief, had each of the defendants carried out proper testing on their products it would have realized the risks of using their products included cardiovascular events

including but not limited to heart attack, stroke and thromboembolism, and that the risks far outweighed any alleged benefits from the products.

- 13. Upon information and belief, each of the defendants, through its agents, employees and representatives, engaged in intentional efforts to hide and withhold from the public safety concerns expressed by its own officials and researchers linking the aforesaid drugs to increased heart risks.
- 14. In reliance on the same, the injured plaintiffs ingested the drugs and continued ingesting the drugs for a period of time as instructed by their respective prescribing physicians.
- 15. For a period of time starting in or about 2001 and continuing thereafter at various times, injured plaintiff HELEN BILIK ingested the drugs Vioxx and Celebrex as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 16. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff ELIZABETH BOONE ingested the drugs Vioxx, Bextra and Celebrex as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 17. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff MARY J. MAHAR ingested the drugs Vioxx and Bextra as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 18. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff CAROLYN S. CROFT ingested the drugs Celebrex and Vioxx as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 19. For a period of time starting in or about 2002 and continuing thereafter at various times, injured plaintiff GERALDINE M. ALAPECK ingested the drugs Vioxx and Bextra at the direction of her physicians and in accordance with the respective manufacturer's instructions.
- 20. For a period of time starting in or about 2002 and continuing thereafter at various times, injured plaintiff DEAN SANTACROSE ingested the drugs Vioxx and Celebrex at the direction of

his physicians and in accordance with the respective manufacturer's instructions.

- 21. For a period of time starting in or about 2003 and continuing thereafter at various times, injured plaintiff STASIA SIMMONS ingested the drugs Vioxx and Bextra at the direction of her physicians and in accordance with the respective manufacturer's instructions.
- 22. Due to safety concerns of an increased risk of cardiovascular events, on or about September 30, 2004, Merck announced a voluntary withdrawal of Vioxx (rofecoxib) from the market, and on or about April 7, 2005, Pfizer withdrew Bextra from the market.
- 23. As a direct and proximate result of the conduct of each of the defendants, the injured plaintiffs sustained severe injuries, which, upon information and belief, are permanent in nature.
- 24. By reason of the foregoing, each of the injured plaintiffs sustained great pain and suffering, and continued to sustain great pain and suffering for a lengthy period of time, and sustained great anxiety and fear of additional adverse medical consequences, and will continue to so suffer in the future.
- 25. By reason of injuries caused by ingestion of the aforesaid drugs, the injured plaintiffs each incurred or may be obligated to pay monies for medical expenses.
- 26. The injuries sustained by the aforesaid plaintiffs and the damages resulting therefrom were caused solely by the defendants' defective products without any fault on the part of the plaintiffs contributing hereto.
- 27. Plaintiffs allege that the limitations on liability set forth in CPLR § 1601 do not apply under the exemptions set forth in CPLR §§ 1602(5), 1602(7) and 1602(11).
 - 28. In the event applicable, plaintiffs rely on the provisions of CPLR §214-c(4).

AS AND FOR A FIRST CAUSE OF ACTION (NEGLIGENCE AND GROSS NEGLIGENCE)

29. Plaintiffs reallege and incorporate herein as if fully set forth herein the allegations in the preceding paragraphs 1 through 29 of this complaint.

- 30. Each of the defendants knew or should have known with the exercise of reasonable care that the products complained of are unreasonably dangerous products, and nevertheless promoted and placed said products into the stream of commerce.
- 31. Prior to the time the injured plaintiffs ingested the products as aforesaid, each of the defendants knew or should have known that a significant portion of the users of the products would be subject to a significant risk and increased risk of serious side effects, including cardiovascular disease and stroke.
- 32. Upon information and belief, each of the defendants failed to carry out adequate investigation including, but not limited to, failing to adequately test their respective products.
- 33. Each of the defendants was further grossly negligent and evinced a reckless disregard for the safety of persons who would be using said products by downplaying, minimizing, and otherwise failing to warn the medical profession, the public in general and each plaintiff in particular about the serious and deadly side effects of their products, while at the same time promoting the drugs on the basis of minor alleged benefits and unsubstantiated or false claims as to efficacy for pain management.
- 34. As a direct and proximate result of the negligence of each of the defendants, the injured plaintiffs were harmed and sustained the injuries as aforesaid due to ingesting the products over a period of time.
- 35. As a result of the foregoing, each of the injured plaintiffs is entitled to compensatory damages from each of the defendants, and to exemplary damages from each of the defendants.

AS AND FOR A SECOND CAUSE OF ACTION (STRICT LIABILITY)

- 36. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
 - 37. At all times herein mentioned, the defendants' respective products were dangerous and

defective, in that any benefit from said products was outweighed by the serious and deadly side effects of said drugs.

- 38. Each of the defendants placed said products into the stream of commerce with reckless disregard for the public safety in that it did not carry out adequate testing, did not timely or adequately continue to test and monitor the safety of the drugs, or take other reasonable steps to assure the products were efficacious for the purpose for which they were intended without subjecting the user to significant and harmful side effects as aforesaid.
- 39. Each of the defendants are strictly liable for the harm the injured plaintiffs sustained as a result of ingesting the products as aforesaid.
- 40. As a result of reckless disregard for the public welfare and welfare of each plaintiff in particular, each of the plaintiffs is entitled to exemplary damages from each of the defendants in addition to compensatory damages sustained as a result of each of the defendants' conduct.

AS AND FOR A THIRD CAUSE OF ACTION (MISREPRESENTATION AND FAILURE TO WARN)

- 41. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 42. Beginning prior to the time the plaintiffs herein ingested the drugs as aforesaid, each of the defendants engaged in a strategy involving aggressively marketing and selling the aforesaid products by falsely misleading potential users as to the safety of the drugs, by promoting the drugs based on unsubstantiated safety claims, and by failing to protect users from serious dangers which each of the defendants knew or should have known to result from use of said products.
- 43. By use of affirmative misrepresentations and omissions, each of the defendants engaged in promotional or advertising programs that falsely and fraudulently sought to create the image and impression that the the aforesaid drugs were safe, known to be safe or had minimal risks to the public

and each plaintiff in particular.

- 44. Upon information and belief, each of the defendants understated downplayed or withheld information concerning health hazards and risks associated with the drugs, as well as the lack of adequate testing and monitoring for safety.
- 45. Each of the defendants failed to provide adequate warnings and/or information concerning the harms or potential harms of and dangers of the use of said products to the public for whom the drugs were not expressly contraindicated, and diluted any warnings by representing that adverse events were not significant for persons likely to be the users of said drugs.
- 46. As a direct and proximate result of the aforesaid failure by each of the defendants to provide appropriate warnings and/or instructions, each plaintiff sustained the harm complained of herein.
- 47. Upon information and belief, at the times relevant to this complaint, each defendant was in possession of information demonstrating serious side effects evidencing the increased risk the drugs posed to patients, or clearly should have been in possession of such information yet continued to market the products by providing false and misleading information with regard to safety as aforesaid, and, despite the same, and despite the fact that there was existing evidence said drugs was in fact dangerous, each defendant downplayed the health hazards and risks associated with the products and in fact deceived the medical community, individual physicians and the public at large including potential users of the products by promoting the same as safe and effective.
- 48. Upon information and belief, each defendant placed profit concerns over and above the safety of the public.
- 49. As a result of each defendant's reckless disregard for the public welfare and welfare of each plaintiff in particular, each of the injured plaintiffs is entitled to an award of exemplary damages from each of the defendants in addition to compensatory damages sustained as a result of said conduct.

AS AND FOR A FOURTH AND SEPARATE CAUSE OF ACTION

(BREACH OF EXPRESS AND IMPLIED WARRANTIES)

- 50. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 51. Each of the defendants expressly and impliedly warranted that their aforesaid drugs were safe when used by patients for whom the drugs were not otherwise contraindicated, including the injured plaintiffs herein.
- 52. Each of the defendants breached such express and implied warranties in that their respective drugs are not safe for the purpose for which intended.
- 53. As a direct and proximate result of the aforesaid breach of express and implied warranties, each injured plaintiff is entitled to an award of compensatory and to an award of exemplary damages, inasmuch as the breach was in reckless disregard of the public health and safety.

AS AND FOR A FIFTH AND SEPARATE CAUSE OF ACTION (VIOLATION OF NEW YORK BUSINESS CORPORATION LAW § 349)

- 54. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 55. Each defendant's conduct as set forth herein constituted deceptive acts or practices and involved an extensive marketing scheme that had a broader impact on consumers at large.
- 56. Each defendant engaged in acts or practices that were deceptive or misleading in that the same were likely to mislead a reasonable consumer acting reasonably under the circumstances to ingest the products and be injured thereby.
 - 57. Each defendant's acts and practices violated New York's Business Corporation Law § 349.
- 58. The injured plaintiffs sustained harm as a direct and proximate result of the deceptive and misleading acts and practices of each of the defendants, and are entitled to compensatory and exemplary damages therefor.

RELIEF REQUESTED

WHEREFORE, the plaintiffs demand judgment against the defendants, jointly and severally, as appropriate, on each cause of action as pled herein as follows:

- (1) Award each of the plaintiffs compensatory damages and exemplary damages against defendants on each of the first through fifth causes of action;
- (2) Award the plaintiffs such other and further relief against the defendants as the Court deems just and proper under the circumstances, including the costs and disbursements of this action.

Dated: April 7, 2005

LAW OFFICE OF RONALD R. BENJAMIN

Attorneys for Plaintiffs 126 Riverside Drive, P. O. Box 607 Binghamton, New York 13902-0607 607/772-1442

PONALD D DENIAMIN

COUNTY	COURT OF THE STATE OF NEW YORK OF NEW YORK	
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	CAROLYN S. CROFT, GERALDINE M.	
	C, DEAN SANTACROSE, and STASIA	
SIMMONS	5,	•• •
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	Plaintiffs,	ACKNOWLEDGHENT OF RECEIPT BY MAIL
	-against-	OF SUMMONS AND COMPLAINT
	~	Index No.: 106237/05
PPIZER,	INC., PHARMACIA CORPORATION,	Date Filed: May 5, 2005
	y-owned subsidiary of PPIZER,	F .
	ind PHARMACIA & UPJOHN COMPANY,	
	Ly-owned subsidiary of PHARMACIA	'LE
CORPORA	ATION, and MERCK & CO., INC.,	GOVEN NEWS
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TO:	Merck & Co., Inc.	GOL. No. 2005
	One Merck Drive	WINT EN YOU.
	P.O. Box 100 W93AB-05	CLEDUNK
	Whitehouse Station, New Jersey .08889-0100	COUNTY C: ERK'S OFF
	I received a summone and complaint in the above	ve captioned matter at
	Please check one of the following:	
	1. X_1 I am not in the military service.	
	2. [] I am in the military service, and my	rank, serial number and branch of service are as
follows	3 :	
	Rank:	
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	TO BE COMPLETED REGARDLES	S OF MILITARY STATUS:
	Date: May 25, 2005	
		١٠.٠)
	(Date this Acknowledgment is execu	cea)
	I affirm the above as true under penalty of p	erjury.
	1/10:1 4 1/ 00	
Signati	ire: Willa D. Hayes	
Print)		
Address		
	One Battery Park Plaza,	
Иате о	t Defendant for which acting: Merck + Co	IK.
Positi	on with Defendant for which acting (i.e., offic	cer, attorney, etc.)
	PLEASE COMPLETE ALL BL	NKS INCLUDING DATES

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS,

Plaintiffs,

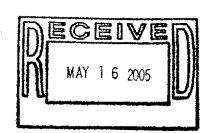
-against-

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PPIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly-owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO., INC.,

Defendants.

Merck & Co., Inc. TO: One Merck Drive P.O. Box 100 WS3AB-05

Whitehouse Station, New Jersey 08889-0100



STATEMENT OF SERVICE BY MAIL Index No.: 106237/05 Date Filed: May 4, 2005

The enclosed summans and complaint are served pursuant to section 312-a of the Civil Practice Law and Rules.

To avoid being charged with the expense of service upon you, you must sign, date and complete the acknowledgment part of this form and mail or deliver one copy of the completed form to the sender within thirty (30) days from the date you receive it. If you wish to consult an attorney, you should do so as soon as possible before the thirty (30) days expire.

If you do not complete and return the form to the sender within thirty (30) days, you (or the party on whose behalf you are being served) may be required to pay expenses incurred in serving the guzmons and complaint in any other manner permitted by law, and the cost of such service as permitted by law may be entered as a judgment against you.

If you have received a complaint with this statement, the return of this statement and acknowledgment does not relieve you of the necessity to answer the complaint or petition. The time to answer expires twenty (20) days after the day you mail or deliver this form to the sender. If you wish to consult an attorney, you should do so as soon as possible before the twenty (20) days.

If you are served on behalf of a corporation , unincorporated association, partnership or other entity, you must indicate under your signature your relationship to the entity. If you are served on behalf of another person and you are authorized to receive process, you must indicate under your signature your authority.

It is a crime to forge a signature or to make a false entry on this statement or on the acknowledgment.

Dated: May 12, 2005

Binghamton, New York

RONALD R. BENJAMIN, ESQ.

LAW OFFICE OF RONALD R. BENJAMIN

Attorney for Plaintiffs

126 Riverside Drive

9.0. Box 607

(607) 772-1442

SUPREME COURT OF THE STATE OF NEW YOR COUNTY OF NEW YORK	RK
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HELEN BILIK, ELIZABETH BOONE, MARY J. : MAHAR, CAROLYN S. CROFT, GERALDINE : M. ALAPECK, DEAN SANTACROSE, and : STASIA SIMMONS, :	No.: 106237/05
Plaintiffs, :	ANSWER AND JURY DEMAND
-against-	OF DEFENDANT MERCK & CO., INC.
PFIZER, INC., PHARMACIA CORPORATION, : a wholly-owned subsidiary of PFIZER, INC., and : PHARMACIA & UPJOHN COMPANY, a : wholly-owned subsidiary of PHARMACIA : CORPORATION, and MERCK & CO, INC., :	FILED JUN 15 2005
Defendants.	JUN 15 2003
X	NEW YORK OUNTY CLERK'S OFFICE

Defendant Merck & Co., Inc. ("Merck"), by its undersigned attorneys, answers the Complaint ("Complaint") herein as follows:

- ١. Denies knowledge and information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 1 of the Complaint.
- 2. The allegations contained in paragraph 2 of the Complaint are not directed toward Merck and therefore no responsive pleading is required.
- 3. The allegations contained in paragraph 3 of the Complaint are not directed toward Merck and therefore no responsive pleading is required.
- 4 The allegations contained in paragraph 4 of the Complaint are not directed toward Merck and therefore no responsive pleading is required.
- 5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place

of business at One Merck Drive, Whitehouse Station, New Jersey and is authorized to do business in the State of New York.

- 6. The allegations contained in paragraph 6 of the Complaint are not directed toward Merck and therefore no responsive pleading is required.
- 7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that Merck is a leading research-driven pharmaceutical products and services company that researches, discovers, develops, manufactures and markets a broad range of innovative pharmaceutical products, including VIOXX®, to improve human health and that VIOXX® is a selective NSAID which reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxegenase-2 ("COX-2").
- 8. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 8 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 8 of the Complaint.
- 9. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 9 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 9 of the Complaint except admits that Merck marketed the prescription medicine VIOXX®.
- 10. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 10 of the

Complaint, and denies each and every allegation directed toward Merck contained in paragraph 10 of the Complaint, except admits that Merck marketed the prescription medication VIOXX®, which was approved by the FDA as safe and effective for certain indicated uses subject to the information contained in the FDA-approved prescribing information. Merck further avers that it provides to the Physicians' Desk Reference a copy for publication of the FDA-approved prescribing information for VIOXX® in effect at the time and respectfully refers the Court to the Physicians' Desk Reference for the actual language and full text of said prescribing information.

- 11. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 11 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 11 of the Complaint.
- Merck lacks knowledge or information sufficient to form a belief as to the 12. truth or falsity of the allegations not directed toward Merck in paragraph 12 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 12 of the Complaint.
- 13. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 13 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 13 of the Complaint.
- 14. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 14 of the

Complaint, and denies each and every allegation directed toward Merck contained in paragraph 14 of the Complaint.

- 15. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 15 of the Complaint.
- 16. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 16 of the Complaint.
- 17. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 17 of the Complaint.
- 18. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 18 of the Complaint.
- 19. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 19 of the Complaint.
- 20. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 20 of the Complaint.
- 21. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 21 of the Complaint.
- 22. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 22 of the Complaint, and denies each and every allegation contained in paragraph 122 of the Complaint and avers that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking VIOXX® compared with those taking placebo. Merck further avers that given the

availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of VIOXX® best served the interests of patients.

- 23. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 23 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 23 of the Complaint.
- 24. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 24 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 24 of the Complaint.
- 25. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 25 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 25 of the Complaint.
- 26. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 26 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 26 of the Complaint.
- 27. The allegations contained in paragraph 27 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

RESPONSE TO "FIRST CAUSE OF ACTION (NEGLIGENCE AND GROSS NEGLIGENCE)"

- 29. With respect to the allegations contained in paragraph 29 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 29 of this Answer with the same force and effect as though set forth here in full.
- 30. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 30 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 30 of the Complaint.
- 31. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 31 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 31 of the Complaint.
- 32. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 32 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 32 of the Complaint.

- 33. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 33 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 33 of the Complaint.
- 34. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 34 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 34 of the Complaint.
- 35. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 35 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 35 of the Complaint.

RESPONSE TO "SECOND CAUSE OF ACTION (STRICT LIABILITY)"

- 36. With respect to the allegations contained in paragraph 36 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 35 of this Answer with the same force and effect as though set forth here in full.
- 37. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 37 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 37 of the Complaint.
- 38. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 38 of the

Complaint, and denies each and every allegation directed toward Merck contained in paragraph 38 of the Complaint.

- 39. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 39 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 39 of the Complaint.
- 40. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 40 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 40 of the Complaint.

RESPONSE TO "THIRD CAUSE OF ACTION (MISREPRESENTATION AND FAILURE TO WARN)"

- 41. With respect to the allegations contained in paragraph 41 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 40 of this Answer with the same force and effect as though set forth here in full.
- 42. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 42 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 42 of the Complaint.
- 43. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 43 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 43 of the Complaint.

- 44. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 44 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 44 of the Complaint.
- 45. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 45 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 45 of the Complaint.
- 46. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 46 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 46 of the Complaint.
- 47. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 47 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 47 of the Complaint.
- Merck lacks knowledge or information sufficient to form a belief as to the 48. truth or falsity of the allegations not directed toward Merck in paragraph 48 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 483 of the Complaint.
- 49. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 49 of the

Complaint, and denies each and every allegation directed toward Merck contained in paragraph 49 of the Complaint.

RESPONSE TO "FOURTH AND SEPARATE CAUSE OF ACTION (BREACH OF EXPRESS AND IMP LIED WARRANTIES)"

- 50. With respect to the allegations contained in paragraph 50 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 49 of this Answer with the same force and effect as though set forth here in full.
- 51. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 51 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 51 of the Complaint.
- 52. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 52 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 52 of the Complaint.
- 53. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 53 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 53 of the Complaint.

RESPONSE TO "FIFTH AND SEPARATE CAUSE OF ACTION (VIOLATION OF NEW YORK BUSINESS CORPORATION LAW § 349)"

54. With respect to the allegations contained in paragraph 54 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 53 of this Answer with the same force and effect as though set forth liere in full.

- 55. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 55 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 55 of the Complaint.
- 56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 56 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 56 of the Complaint.
- Merck lacks knowledge or information sufficient to form a belief as to the 57. truth or falsity of the allegations not directed toward Merck in paragraph 57 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 57 of the Complaint.
- 58. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations not directed toward Merck in paragraph 58 of the Complaint, and denies each and every allegation directed toward Merck contained in paragraph 58 of the Complaint.

RESPONSE TO "RELIEF REQUESTED"

59. Plaintiffs' "Relief Requested" section of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in the "Relief Requested" section of Plaintiffs' Complaint and denies that Plaintiffs are entitled to the relief requested.

AS FOR A FIRST DEFENSE, MERCK ALLEGES:

60. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

AS FOR A SECOND DEFENSE, MERCK ALLEGES:

61. The Complaint fails to state a claim upon which relief can be granted.

AS FOR A THIRD DEFENSE, MERCK ALLEGES:

62. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

AS FOR A FOURTH DEFENSE, MERCK ALLEGES:

63. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

AS FOR A FIFTH DEFENSE, MERCK ALLEGES:

64. To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

AS FOR A SIXTH DEFENSE, MERCK ALLEGES:

65. To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of VIOXX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

AS FOR A SEVENTH DEFENSE, MERCK ALLEGES:

66. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiffs.

AS FOR AN EIGHTH DEFENSE, MERCK ALLEGES:

67. Any liability that might otherwise be imposed upon this defendant is subject to reduction by the application of the doctrine of comparative negligence.

AS FOR A NINTH DEFENSE, MERCK ALLEGES:

68. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

AS FOR A TENTH DEFENSE, MERCK ALLEGES:

69. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

AS FOR AN ELEVENTH DEFENSE, MERCK ALLEGES:

70. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by

Plaintiffs' inisuse or abuse of VIOXX®.

AS FOR A TWELFTH DEFENSE, MERCK ALLEGES:

71. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

AS FOR A THIRTEENTH DEFENSE, MERCK ALLEGES:

72. To the extent that Plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and lack of privity and because the alleged warranties were disclaimed.

AS FOR A FOURTEENTH DEFENSE, MERCK ALLEGES:

73. Plaintiffs' claims are barred, in whole or in part, under the applicable state law because VIOXX® was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A FIFTEENTH DEFENSE, MERCK ALLEGES:

74. Plaintiffs' claims are barred in whole or in part by the First Amendment.

AS FOR A SIXTEENTH DEFENSE, MERCK ALLEGES:

75. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack capacity and standing to bring such claims.

AS FOR AN SEVENTEENTH DEFENSE, MERCK ALLEGES:

76. Plaintiffs' claims are barred in whole or in part because the product at

issue was made in accordance with the state of the art at the time it was manufactured.

AS FOR A EIGHTEENTH DEFENSE, MERCK ALLEGES:

77. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, any award of punitive damages is barred under the relevant state law.

AS FOR A NINETEENTH DEFENSE, MERCK ALLEGES:

78. Plaintiffs' demands for punitive damages are barred because VIOXX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

AS FOR A TWENTIETH DEFENSE, MERCK ALLEGES:

79. Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

AS FOR A TWENTY-FIRST DEFENSE, MERCK ALLEGES:

80. Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of VIOXX® and any other drug or pharmaceutical preparation Plaintiffs allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

AS FOR A TWENTY-SECOND DEFENSE, MERCK ALLEGES:

81. Plaintiffs' claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

AS FOR A TWENTY-THIRD DEFENSE, MERCK ALLEGES:

82. Plaintiffs' claims are barred in whole or in part under comment f to

Section 6 of the Restatement (Third) of Torts: Product Liability.

AS FOR A TWENTY-FOURTH DEFENSE, MERCK ALLEGES:

83. This case is more appropriately brought in a different venue.

AS FOR A TWENTY-FIFTH DEFENSE, MERCK ALLEGES:

84. Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b) and Rule 3013 of the New York Civil Practice Law and Rules.

AS FOR A TWENTY-SIXTH DEFENSE, MERCK ALLEGES:

85. To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

AS FOR A TWENTY-SEVENTH DEFENSE, MERCK ALLEGES:

86. To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

AS FOR A TWENTY-EIGHTH DEFENSE, MERCK ALLEGES:

87. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

AS AND FOR A TWENTY-NINTH DEFENSE, MERCK ALLEGES:

88. Plaintiffs' claims are barred in whole or in part because Plaintiffs have

failed to mitigate the alleged damages.

AS AND FOR A THIRTIETH DEFENSE, MERCK ALLEGES:

89. There is no technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of VIOXX®.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'
Complaint with prejudice and awarding Merck its reasonable costs and disbursements,
together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Dated: June <u>13</u>, 2005

New York, New York

Respectfully submitted,

HUGHES HUBBARD & REED LLP

Theodore V. H. Mayer

Vilia B. Hayes Robb W. Patryk

One Battery Park Plaza New York, New York 10004-1482 (212) 837-6000

Attorneys for Defendant Merck & Co., Inc.

SUPREME COURT OF THE STATE OF NEW Y	ORK	
COUNTY OF NASSAU		
	- X	
	:	
HELEN BILIK, ELIZABETH BOONE, MARY J	. :	
MAHAR, CAROLYN S. CROFT, GERALDINE	:	
M. ALAPECK, DEAN SANTACROSE, and	:	
STASIA SIMMONS,	:	N
	:	No.: 106237/05
Plaintiffs,	:	
	:	
-against-	:	AFFIDAVIT OF SERVICE
PFIZER, INC., PHARMACIA CORPORATION,	:	
a wholly-owned subsidiary of PFIZER, INC., and	_	
PHARMACIA & UPJOHN COMPANY, a	:	
wholly-owned subsidiary of PHARMACIA		
CORPORATION, and MERCK & CO, INC.,	:	
ord ordinary and markets of the same		
Defendants.	:	
	- X	

SARAH A. BINDER, being duly sworn, deposes and says that she is over the age of 18 years and not a party to this action, that she is associated with the firm of Hughes Hubbard & Reed, counsel for Defendant, and that, on June 13, 2005, she served a true and accurate copy of the Answer and Jury Demand of Defendant Merck & Co., Inc. via first-class mail, postage prepaid, on plaintiff's counsel, Ronald R. Benjamin, Law Office of Ronald R. Benjamin, 126 Riverside Drive, Binghamton, New York 13902 and on counsel for Defendant Pfizer, Inc., Christopher Strongosky, DLA Piper Rudnick Gray Cary US LLP, 1251 Avenue of the Americas, New York, New York 10022.

Sarah A. Binder

Sworn to before me this /3 day of June, 2005

ALYSSA BENJAMIN Notary Public, State of New York No. 02BE6123029 Qualified In New York County Commission Expires February 28, 2009 SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK HELEN BILIK, ELIZABETH BOONE, MARY J.: MAHAR, CAROLYN S. CROFT, GERALDINE No.: 05-106237 M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS Plaintiffs, -against-PFIZER, INC., PHARMACIA CORPORATION, FILED a wholly-owned subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly-owned subsidiary of PHARMACIA JUN 15 2005 CORPORATION, and MERCK & CO, INC., MEM YORK Defendants. COUNTY CLERK'S OFFICE

FIRST SET OF INTERROGATORIES TO PLAINTIFFS
HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S.
CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA
SIMMONS PROPOUNDED BY DEFENDANT MERCK & CO., INC.

Defendant Merck & Co., Inc. ("Merck") propounds the following interrogatories to plaintiffs Helen Bilik, Elizabeth Boone, Mary J. Mahar, Carolyn S. Croft, Geraldine M. Alapeck, Dean Santacrose, and Stasia Simmons pursuant to Sections 3102 and 3130-3132 of the Civil Practice Law and Rules. Each plaintiff is requested to respond separately and in writing on his or her behalf within twenty (20) days of service.

The following Definitions and Instructions are applicable and are expressly incorporated into these Interrogatories:

DEFINITIONS AND INSTRUCTIONS

1. "Merck & Co., Inc." and "Merck" means any of the subsidiaries, divisions, departments, affiliates, predecessors, successors or offices of the defendant and

by whatever name known, and all present and former officers, directors, employees, trustees, principals, agents, and representatives of Merck, as well as any person acting or purporting to act on its behalf.

- "Plaintiff" or "you" or "your" or "yourself" means plaintiff, any of 2. his or her agents, representatives or assigns, as well as any person acting or purporting to act on his or her behalf.
- 3. "VIOXX®" means the prescription drug with the chemical name rofecoxib which is the subject of this lawsuit.
- "Document" means any writing or record of any type, however produced and whatever the medium on which it was produced or reproduced, and includes, without limitation, the original and any non-identical copy (whether different from the original because of handwritten notes or underlying on the copy or otherwise) and all drafts of papers, letters, telegrams, telexes, notes, notations, memoranda of conversations or meeting, calendars, diaries, minutes of meetings, interoffice communications, electronic mail, message slips, notebooks, agreements, reports, articles, books, tables, charts, schedules, memoranda, medical records, x-rays, advertisements, pictures, photographs, films, accounting books or records, billings, credit card records, electrical or magnetic recordings or tapes, or any other writings, recordings, or pictures of any kind or description.
- 5. The term "communications" means all occasions on which information was conveyed from one person to another (a) by means of a document, or (b) verbally, including by means of a telephone or other mechanical or electronic device.

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6. As used herein, the term "person" shall include, wherever appropriate, not only a natural person but also a corporation, partnership, unincorporated association or other association of persons. However, a request for identification of a person having knowledge of facts or custody of a document shall be construed to refer to a natural person.

- 7. A response to a request contained in these Interrogatories to "identify" a document shall be sufficient if the individual having custody of the document is identified by name and address, and the document is identified or described by (a) the date, (b) the author, (c) the addressee(s), (d) the type of document (i.e., letter, memorandum, note, etc.), (e) the subject matter, and (f) the number of pages. In lieu of identifying a document, you may attach a copy of such document or documents to your answers to these Interrogatories.
- 8. A request to "identify" a person shall be construed as a request for (a) the full name of such person, (b) all other names which such person has used for him or herself, (c) the social security number of such person, (d) the date and place of birth of such person, (e) the present employer of such person, (f) the present office or business address and business telephone number of such person, (g) the present residential address and residential telephone number of such person, (h) the nature the relationship between the plaintiff and such person, (i) the dates of commencement and termination of that relationship, and (j) the reason for the termination of that relationship. If you do not know or cannot determine the present address, telephone number or present employer of any person referred to in your answers to these Interrogatories, please give the last known address, telephone number or employer.

- 9. The term "describe in detail" means: (a) describe fully by reference to underlying facts rather than by ultimate facts or conclusions of fact or law, (b) state for each such fact the (1) time, (2) place, and (3) manner of said fact, (c) identify all persons involved, and (d) identify all documents that support, contradict, refer, relate, or mention such facts.
- If you object to any Interrogatory or any subpart thereof on the 10. grounds that it calls for disclosure of information which you claim is privileged, then answer such Interrogatory or subpart as follows: (a) furnish all information and facts called for by such Interrogatory or subpart which you do not claim is privileged, and (b) for each communication, recommendation, fact or advice which you claim is privileged, state the basis for your claim of privilege.
- 11. Throughout these interrogatories, including the definition of terms, words used in the masculine gender include the feminine; and words used in the singular include the plural. Where the word "or" appears herein, the meaning intended is the logical inclusion "or" i.e., "and/or." Where the word "include" or "including" appears, the meaning intended is "including, but not limited to."
- 12. When requested to "state each fact" or the "facts upon which you rely" relating to any allegation, fact, legal theory, contention or denial, please furnish a full and complete statement of the factual basis of any such allegation, fact, legal theory, contention or denial, the reason or rationale that such facts so relate or pertain and how such facts so relate or pertain.

INTERROGATORIES

<u>INTERROGATORY 1</u>:

Please identify yourself, including your full name; all other names you have used or by which you have been known and the period of time during which you were known by such other names; your address; the date and place of your birth; your social security number and, if different, your driver's license number.

ANSWER:

INTERROGATORY NO. 2:

Please describe your educational background, including the name and address of each grade school, high school, college or university, trade school, or graduate school attended; the inclusive dates of attendance; list any majors(s), minor(s), and the degree(s) received.

ANSWER:

INTERROGATORY NO. 3:

Please describe your employment history since age 18, identifying each employer (or period of self-employment), the inclusive dates of each employment, your job title, a description of your duties for each employment, the amount or rate of compensation for each employment, and your reason for leaving each employment.

INTERROGATORY NO. 4:

Describe in detail all injuries, diseases, illnesses, disabilities or other medical conditions experienced by you since January 1, 1995. (See definition 9.)

ANSWER:

INTERROGATORY NO. 5:

Please identify by name, address, telephone number, and specialty, if applicable, each and every physician or other healthcare provider whom you consulted, or who treated or examined you for any reason whatsoever since January 1, 1995, and describe in detail the reasons you sought treatment or consultation, the date(s) of the treatment or consultation, all tests performed, the diagnosis, and the medication prescribed. (See definitions 8 & 9.)

ANSWER:

INTERROGATORY NO. 6:

Describe in detail your medication history, other than VIOXX®, including a list of all medications (prescription and non-prescription), and drugs (legal or illegal) that you used since January 1, 1995, the reason each medicine, medication, and/or drug was used, and for each medication or drug, identify its brand or generic name; if it was prescribed, the name and address of the person prescribing it; the name and address of the pharmacy from which such medication was purchased; the dates on which you took the

drug, the amounts and dosage of each drug taken, and the dates and reasons for which you stopped taking it; and the nature of any reaction, including any allergic reaction or side effect experienced by you. (See definition 9.)

ANSWER:

INTERROGATORY NO. 7:

Please identify each and every healthcare provider who prescribed VIOXX® or provided samples of VIOXX® to you. For each healthcare provider, state the condition for which VIOXX® was prescribed or was provided, the dates such prescriptions were issued or such samples were provided, and the dosages. (See definition 8.)

ANSWER:

INTERROGATORY NO. 8:

State the dates on which you started and stopped treatment with VIOXX®, the dosage you were taking, and whether any physician increased or decreased your original prescription at any time. If you, on your own, changed your dosage of VIOXX® or the frequency of the dosage at any time from the dosage recommended by the prescribing physician, state the date on which you made each change, and the actual amount of VIOXX® consumed by you each day. Please also state whether your

VIOXX® usage was uninterrupted. If your VIOXX® usage was interrupted, please state what was the longest period of continuous usage.

ANSWER:

INTERROGATORY NO. 9:

State the dates on which you started and stopped treatment with Celebrex®, the dosage you were taking, and whether any physician increased or decreased your original prescription at any time. If you, on your own, changed your dosage of Celebrex®, or the frequency of the dosage at any time from the dosage recommended by the prescribing physician, state the date on which you made each change, and the actual amount of Celebrex® consumed by you each day.

ANSWER:

INTERROGATORY NO. 10:

State the dates on which you started and stopped treatment with Bextra®, the dosage you were taking, and whether any physician increased or decreased your original prescription at any time. If you, on your own, changed your dosage of Bextra®, or the frequency of the dosage at any time from the dosage recommended by the prescribing physician, state the date on which you made each change, and the actual amount of Bextra® consumed by you each day.

INTERROGATORY NO. 11:

Describe in detail each injury, illness, disease or condition (i.e., sign or symptom, whether mental, physical or emotional) that you claim to have resulted from your use of VIOXX®; the dates of onset for each injury, illness, disease or condition; and set forth the name and address of all physicians or other healthcare providers with whom you consulted or from whom you sought treatment for these conditions. (See definition 8.)

ANSWER:

INTERROGATORY NO. 12:

For each injury identified in Interrogatory No. 11, please identify all healthcare providers and experts who will support the claim that VIOXX® caused such injury, the substance of such opinions, and any facts or documents upon which such opinions are based. Attach to your interrogatory answers a copy of all written reports supporting this claim. (See definition 7.)

ANSWER:

INTERROGATORY NO. 13:

Identify any member of your family who has experienced cardiovascular events, including heart attacks and strokes, or any other medical condition(s) similar to

the condition(s) experienced by you, and, for each person so identified, describe in detail the nature of such medical condition(s). (See definitions 8 & 9.)

ANSWER:

INTERROGATORY NO. 14:

Separately itemize all expenses and losses that you claim to have incurred or expect to incur as a result of the injuries you claim that you suffered from taking VIOXX®, including the dollar amount of hospital bills and identity of the hospital; medical bills with the names and addresses of the persons requesting payment; nursing bills with the names and addresses of the persons requesting payment; loss of earnings including the names and addresses of employers; and any other similar expenses and damages, specifying type, amount and person to whom such amount is due.

ANSWER:

INTERROGATORY NO. 15:

If you have ever been given disability ratings for accident, health or life insurance, please identify the healthcare provider that assigned each such rating, the date on which you were given each disability rating, and the reason for which you were given each disability rating.

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INTERROGATORY NO. 16:

State whether you have undergone any additional physical examinations, including examinations in connection with employment or any application for employment or for life insurance since January 1, 1995, and if so, state the date of any such examination, who conducted the examination, on whose behalf the examination was made, whether there is a report of such physical examination, and if any such physical examination resulted in action being taken on your behalf or against you, please describe such action.

ANSWER:

INTERROGATORY NO. 17:

Identify each carrier or plan that at any time has provided you with or has rejected your application for life, medical, health, disability and/or compensation coverage, either individually or as a member of an insured family, including group insurance coverage under policies of insurance issued to or on behalf of a spouse or other family member, and as part of your response, include any applicable policy or identification number. If the application was rejected, please state:

- (a) The date of rejection;
- (b) The type of insurance for which you applied;
- (c) The name and address of the insurance company with which the application was filed; and
- (d) The reason given for the rejection.

. . .

INTERROGATORY NO. 18:

Describe in detail every written claim or demand for compensation you have made, including, but not limited to, pre-lawsuit demands to settle, lawsuits, workers' compensation claims, social security disability claims, and/or claims for veteran's benefits including the nature of the proceeding; the date, time, and place of the event for which damages were sought; the name, address, and telephone number of each person against whom the claim was made; the name, address, and telephone number of any attorney; and whether the claim has been resolved or is pending; the caption and case number of the action; the court or tribunal in which the action was pending and the date it was filed; and the disposition of the action. (See definition 9.)

ANSWER:

INTERROGATORY NO. 19:

Identify all facts upon which you rely to support your contention that VIOXX® caused or contributed to your alleged injuries. Identify any other factors that you believe may have contributed to your injuries.

INTERROGATORY NO. 20:

Since you have claimed injuries resulting from the ingestion of VIOXX®, Celebrex®, and/or Bextra®, please identify what you claim is the relative culpability of each defendant and the facts upon which you rely to hold both defendants jointly liable pursuant to C.P.L.R. Article 16.

ANSWER:

INTERROGATORY NO. 21:

Describe in detail each and every fact upon which you base any claim that VIOXX® was defective and/or dangerous. (See definition 9.)

ANSWER:

INTERROGATORY NO. 22:

For each instance that you claim that a doctor prescribed any VIOXX® for you, state whether the prescribing doctor gave you any oral or written warning about the potential side effects of the drug or stated any precautions, and if so, state in detail and completely the substance of the warning(s). Identify any documents containing or referring to such warnings or precautions.

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INTERROGATORY NO. 23:

Describe in detail any warning you claim was defective and/or inadequate concerning VIOXX®; and how the warning was inadequate in light of medical knowledge concerning VIOXX® at the time it was prescribed to you; and a verbatim statement of the warning that you or your experts contend is an adequate warning, how it would have prevented your injuries or damages, whether such warning should have been written or oral, and when and to whom it should have been provided. (See definition 9.)

ANSWER:

INTERROGATORY NO. 24:

Set forth with particularity each and every act or omission upon which you base any claim that Merck was negligent in the manufacture, design, production, testing, studying, researching, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of VIOXX®. Identify what you contend in paragraph 12 of the Complaint would have been the "proper testing" of this medication. State the name and title of each person who performed an alleged negligent act or omission.

INTERROGATORY NO. 25:

Identify all persons whom you contend engaged in intentional efforts to hide and withhold from the public safety concerns linking VIOXX® to increased heart risks as alleged in paragraph 13 of the Complaint. Describe specifically and identify each person responsible and the date of each and every alleged intentional act.

ANSWER:

INTERROGATORY NO. 26:

Please identify all communications by you or any member of your family, whether oral, written or electronic (including communications as part of internet "chat rooms" or e-mail groups), with doctors, Merck representatives, or other persons not including your counsel, regarding VIOXX®, your injuries, or this case.

INTERROGATORY NO. 27:

Describe any and all contacts that you had with any VIOXX®-related advertising, marketing and promotion. List all advertisements, including television, radio, and print, with which you came in contact, including the date on which you were exposed to such advertising. Please identify with specificity the advertising upon which you relied when ingesting VIOXX®.

ANSWER:

INTERROGATORY NO. 28:

Please describe in detail each alleged misrepresentation or omission relative to VIOXX® that you contend was made to you and the general consuming public. For each statement, identify the maker of the statement, the person(s) to whom the statement was made, the circumstances under which such misrepresentation was made, the date(s) upon which such misrepresentation was made or published, and the publication, advertisement, press release, TV ad or other vehicle through which such misrepresentation was disseminated. For each statement that you contend was fraudulently made, please state the basis for your contention that these statements were made with reckless disregard to their truth.

INTERROGATORY NO. 29:

Please state each fact upon which you base your claim that Merck breached an express or implied warranty of fitness and/or merchantability, and identify all witnesses and documents on which you will rely in support of your claim.

ANSWER:

INTERROGATORY NO. 30:

Identify all information demonstrating that knowledge of the "serious side effects" of VIOXX® that you contend in paragraphs 11 and 31 of the Complaint was in Defendant's possession and was not disclosed adequately to the medical community, individual physicians and the public.

ANSWER:

INTERROGATORY NO. 31:

Please state each and every fact and circumstance upon which you base any claim for exemplary damages, including the identity of any witnesses who will testify in support of your allegations of fraud, ill-will, recklessness, gross negligence, and willful or intentional disregard of plaintiff's individual rights. Please provide a full description of the acts or omissions that you allege demonstrate such conduct and any documents upon which you rely in support of said allegations.

INTERROGATORY NO. 32:

Provide the factual basis and a computation for each category of damages you claim and identify all witnesses who will testify in support of each category of damages and all documents upon which you will rely in support of each category of damages.

ANSWER:

INTERROGATORY NO. 33:

Do you rely on any statutes, codes, standards, regulations, rules, texts, medical journals, medical articles, or treatises to establish any alleged defect or unreasonably dangerous condition of VIOXX®? If so, identify each such document and the appropriate section or page number on which you rely.

ANSWER:

INTERROGATORY NO. 34:

Please describe in detail all deceptive acts or practices that you contend violated New York General Business Law §349.

INTERROGATORY NO. 35:

Please describe all facts upon which you rely to support a loss of consortium claim, related but not limited to any changes in your daily activities, the nature of your relationship with your spouse, and your ability to enjoy life as result of the injuries you allegedly have sustained as a result of your use of VIOXX®.

Dated: New York, New York June 13, 2005

HUGHES HUBBARD & REED LLP

Vilia B. Hayes

Attorneys for Defendant

Merck & Co., Inc.

One Battery Park Plaza New York, New York 10004

(212) 837-6000

TO: Ronald R. Benjamin Law Office of Ronald R. Benjamin 126 Riverside Drive P.O. Box 607 Binghamton, NY 13902-0607

COUNTY CLERK'S INDEX No. 106237/05

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COUNTY OF NEW YORK

MAHAR, CAROLYN S. CROFT, GERALDINE M. SIMMONS, HELEN BILIK, ELIZABETH BOONE, MARY J. ALAPECK, DEAN SANTACROSE and STASIA

- against -

Plaintiffs,

and MERCK & CO., INC., owned subsidiary of PHARMACIA CORPORATION, PHARMACIA & UPJOHN COMPANY, a whollywholly-owned subsidiary of PFIZER, INC., and PFIZER, INC., PHARMACIA CORPORATION, a

100 CO *OFFICE COMBINED DEMANDS OF DEFENDANT 500 MERCK & CO., INC. ORIGINAL Defendants

Hughes Hubbard & Reed LLP

One Battery Park Plaza New York, New York 10004-1482 Telephone: 212 837-6000

Vilia B. Hayes, Esq. Attorneys for Defendan MERCK & CO., INO

By:

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ATTACH RIDER SHEET IF NECESSARY TO PROVIDE REQUIRED INFORMATION

ATTORNEY FOR

RIDER SHEET

Attorney for Plaintiffs:

Ronald R. Benjamin, Esq. LAW OFFICE OF RONALD R. BENJAMIN 126 Riverside Drive, P.O. Box 607 Binghamton, New York 13902-0607 (607) 772-1442

Attorneys for Pfizer Defendants:

Amy W. Schulman, Esq. Loren H. Brown, Esq. Stephen P. McLaughlin, Esq. DLA PIPER RUDNICK GRAY CARY US LLP 1251 Avenue of the Americas New York, New York 10020 (212) 835-6000

SIDLEY AUSTIN BROWN & WOOD LLP 787 Seventh Avenue New York, NY 10019 (212) 839-5300

Attorneys for Defendant Merck & Co., Inc.:

Vilia B. Hayes, Esq. HUGHES HUBBARD & REED LLP One Battery Park Plaza New York, New York 10004 (212) 837-6000

AFFIDAVIT OF SERVICE

STATE OF NEW YORK) : ss.:
COUNTY OF NEW YORK)

Nicole L. Wilson, being duly sworn, deposes and says: 1 am over the age of 18 years old and not a party to this action. On the 20th day of July, 2005, I caused to be served a true copy of the foregoing Pfizer DEFENDANTS' REQUEST FOR JUDICIAL INTERVENTION on all counsel by mail at the following addresses:

Ronald R. Benjamin, Esq.
LAW OFFICES OF RONALD R. BENJAMIN
126 Riverside Drive
P.O. Box 607
Binghamton, New York 13902

Vilia B. Hughes, Esq. HUGHES HUBBARD & REED, LLP One Battery Park Plaza New York, New York 10004

the addresses designated by said attorneys for that purpose. Service was completed by depositing true copies of same enclosed in postpaid properly addressed wrappers, in an official depository under the exclusive care and custody of the United States Postal Service.

Nicole L. Wilson

Sworn to before me this 20th day of July, 2005

Notary Public

RACHEL MARIN
Notary Public, State of New York
No. 01 MA6124170
Qualified in New York County
Commission Expires March 21, 2009

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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE and STASIA SIMMONS,

Index No. 106237/05

Plaintiffs,

-against-

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly-owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO., INC.,

NOTICE OF MOTION

Defendants.

PLEASE TAKE NOTICE that upon the Affirmation of Stephen P. McLaughlin, dated July 20, 2005, and the exhibits annexed thereto, the Memorandum of Law submitted herewith, and all pleadings and proceedings had herein, the undersigned will move this Court on behalf of Defendants Pfizer, Inc., Pharmacia Corporation, and Pharmacia & Upjohn LLC at the Courthouse, located at 60 Centre Street, New York, New York at the Motion Support Office Courtroom, Room 130, on the 29th day of September, 2005, at 9:30 a.m., or as soon thereafter as counsel may be heard, for an order, pursuant to CPLR § 3211, 3013 and 3016(b), dismissing the Complaint in this action, and granting such other, further, and different relief as the Court may deem just and proper.

PLEASE TAKE FURTHER NOTICE that, pursuant to CPLR 2214(b), answering papers are required to be served upon the undersigned at least seven (7) days before the return date of this motion.

Dated: New York, New York July 20, 2005 Amy W. Schulman
Loren H. Brown
Stephen P. McLaughlin
DLA PIPER RUDNICK GRAY CAROUS LLP
1251 Avenue of the Americas
New York, New York 10020
(212) 835-6000

SIDLEY AUSTIN BROWN & WOOD LLP 787 Seventh Avenue New York, NY 10019 (212) 839-5300

Attorneys for Defendants Pfizer, Inc., Pharmacia Corporation, and Pharmacia & Upjohn LLC

TO: Ronald R. Benjamin, Esq.
LAW OFFICES OF RONALD R. BENJAMIN
126 Riverside Drive
P.O. Box 607
Binghamton, New York 13902-0607

Attorney for Plaintiffs

Vilia B. Hayes, Esq. HUGHES HUBBARD & REED, LLP One Battery Park Plaza New York, New York 10004

Attorneys for Defendant Merck & Co., Inc.

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J.
MAHAR, CAROLYN S. CROFT, GERALDINE M.
ALAPECK, DEAN SANTACROSE, AND STASIA

Index No. 106237/05

Plaintiffs,

-against-

SIMMONS,

AFFIRMATION OF STEPHEN P. MCLAUGHLIN

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly-owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO., INC.,

Defendants.	
	-X

STEPHEN P. McLAUGHLIN, an attorney duly admitted to practice law before the courts of the State of New York, hereby affirms under the penalties of perjury as follows:

- I am of counsel with the firm of DLA Piper Rudnick Gray Cary US LLP, attorneys for Defendants Pfizer, Inc., Pharmacia Corporation, and Pharmacia & Upjohn LLC ("Pfizer Defendants"). I submit this Affirmation to place before the Court certain documents in support of Pfizer Defendants' Motion to Dismiss the Complaint in this action.
 - 2. Attached as Exhibit A is a copy of the Complaint submitted in this action.
 - 3. Attached as Exhibit B is a true and correct copy of the Decision & Order of the

Hon. Faviola A. Soto, dated June 23, 2005, in <u>Barbara Jaros, et al., v. Pfizer Inc., et al.</u>, Index Number 116110/04, New York Supreme Court for the County of New York.

Dated: New York, New York July 20, 2005

Stephen P. McLaughlin, Esq.

STATE OF NEW YORK: SUPREME COURT COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN'S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS,

COMPLAINT

Plaintiffs.

-VS-

Index No.:

Date Filed:

PFIZER, INC., PHARMACIA CORPORATION, a whollyown subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO, INC,

Defendants.

Plaintiffs HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS, by and through counsel, the Law Office of Ronald R. Benjamin, complaining of each defendant, allege as follows:

- 1. Plaintiffs are and at all times relevant herein were residents of and domiciled in the State of New York.
- 2. Upon information and belief, defendant PFIZER INC., is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York, and is authorized to do and doing business in the State of New York with the county of its principal office registered as New York County.
- 3. Upon information and belief, defendant PHARMACIA & UPJOHN COMPANY is a wholly-owned subsidiary of PHARMACIA CORPORATION, and at times relevant to this

complaint, each was a foreign corporation incorporated in the State of Delaware, and authorized to do business in the State of New York, registered in or with its principal office located in New York County.

- 4. Upon information and belief, as the result of a corporate merger between Pfizer, Inc., and Pharmacia Corporation in or about April 2004, Pharmacia Corporation which is a wholly-owned subsidiary of Pfizer, Inc., and, as a result thereof, Pfizer, Inc., is legally responsible for all obligations, debts and liabilities of Pharmacia Corporation and Pharmacia & Upjohn Company, and is the successor in interest and real party to Pharmacia Corporation and Pharmacia & Upjohn Company (hereafter collectively referred to as "Pfizer defendants").
- Upon information and belief, at all times relevant hereto defendant MERCK & CO. 5. INC. (hereafter "Merck" or defendant), was and is a foreign corporation by virtue of being incorporated in New Jersey, and has its principal place of business at One Merck Drive, P.O. Box 100, WS3AB-05 Whitehouse Station, New Jersey 08889-01000, and is authorized to do business in the State of New York, with its registered principal office located at 111 Eighth Avenue, New York, NY 10011, in the County of New York.
- 6. At all relevant times herein mentioned the Pfizer defendants engaged in manufacture, design, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of their respective pharmaceutical products including the nonsteroidal anti-inflammatory arthritis and acute pain medications CELEBREX (celecoxib) and BEXTRA (valdecoxib), which are selective inhibitors of cyclo-oxygenase 2 (COX-2), for ultimate sale and/or use in the United States of America as well as in countries throughout the world.
- 7. At all relevant times herein mentioned the defendant Merck engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products including the non-

- including but not limited to heart attack, stroke and thromboembolism, and that the risks far outweighed any alleged benefits from the products.
- 13. Upon information and belief, each of the defendants, through its agents, employees and representatives, engaged in intentional efforts to hide and withhold from the public safety concerns expressed by its own officials and researchers linking the aforesaid drugs to increased heart risks.
- 14. In reliance on the same, the injured plaintiffs ingested the drugs and continued ingesting the drugs for a period of time as instructed by their respective prescribing physicians.
- 15. For a period of time starting in or about 2001 and continuing thereafter at various times, injured plaintiff HELEN BILIK ingested the drugs Vioxx and Celebrex as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 16. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff ELIZABETH BOONE ingested the drugs Vioxx, Bextra and Celebrex as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 17. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff MARY J. MAHAR ingested the drugs Vioxx and Bextra as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 18. For a period of time starting in or about 1999 and continuing thereafter at various times, injured plaintiff CAROLYN S. CROFT ingested the drugs Celebrex and Vioxx as directed by her physicians and in accordance with the respective manufacturer's instructions.
- 19. For a period of time starting in or about 2002 and continuing thereafter at various times, injured plaintiff GERALDINE M. ALAPECK ingested the drugs Vioxx and Bextra at the direction of her physicians and in accordance with the respective manufacturer's instructions.
- 20. For a period of time starting in or about 2002 and continuing thereafter at various times, injured plaintiff DEAN SANTACROSE ingested the drugs Vioxx and Celebrex at the direction of

his physicians and in accordance with the respective manufacturer's instructions.

- 21. For a period of time starting in or about 2003 and continuing thereafter at various times. injured plaintiff STASIA SIMMONS ingested the drugs Vioxx and Bextra at the direction of her physicians and in accordance with the respective manufacturer's instructions.
- 22. Due to safety concerns of an increased risk of cardiovascular events, on or about September 30, 2004, Merck announced a voluntary withdrawal of Vioxx (rofecoxib) from the market, and on or about April 7, 2005, Pfizer withdrew Bextra from the market.
- 23. As a direct and proximate result of the conduct of each of the defendants, the injured plaintiffs sustained severe injuries, which, upon information and belief, are permanent in nature.
- 24. By reason of the foregoing, each of the injured plaintiffs sustained great pain and suffering, and continued to sustain great pain and suffering for a lengthy period of time, and sustained great anxiety and fear of additional adverse medical consequences, and will continue to so suffer in the future.
- 25. By reason of injuries caused by ingestion of the aforesaid drugs, the injured plaintiffs each incurred or may be obligated to pay monies for medical expenses.
- 26. The injuries sustained by the aforesaid plaintiffs and the damages resulting therefrom were caused solely by the defendants' defective products without any fault on the part of the plaintiffs contributing hereto.
- 27. Plaintiffs allege that the limitations on liability set forth in CPLR § 1601 do not apply under the exemptions set forth in CPLR §§ 1602(5), 1602(7) and 1602(11).
 - 28. In the event applicable, plaintiffs rely on the provisions of CPLR §214-c(4).

AS AND FOR A FIRST CAUSE OF ACTION (NEGLIGENCE AND GROSS NEGLIGENCE)

29. Plaintiffs reallege and incorporate herein as if fully set forth herein the allegations in the preceding paragraphs 1 through 29 of this complaint.

- 30. Each of the defendants knew or should have known with the exercise of reasonable care that the products complained of are unreasonably dangerous products, and nevertheless promoted and placed said products into the stream of commerce.
- 31. Prior to the time the injured plaintiffs ingested the products as aforesaid, each of the defendants knew or should have known that a significant portion of the users of the products would be subject to a significant risk and increased risk of serious side effects, including cardiovascular disease and stroke.
- 32. Upon information and belief, each of the defendants failed to carry out adequate investigation including, but not limited to, failing to adequately test their respective products.
- 33. Each of the defendants was further grossly negligent and evinced a reckless disregard for the safety of persons who would be using said products by downplaying, minimizing, and otherwise failing to warn the medical profession, the public in general and each plaintiff in particular about the serious and deadly side effects of their products, while at the same time promoting the drugs on the basis of minor alleged benefits and unsubstantiated or false claims as to efficacy for pain management.
- 34. As a direct and proximate result of the negligence of each of the defendants, the injured plaintiffs were harmed and sustained the injuries as aforesaid due to ingesting the products over a period of time.
- 35. As a result of the foregoing, each of the injured plaintiffs is entitled to compensatory damages from each of the defendants, and to exemplary damages from each of the defendants.

AS AND FOR A SECOND CAUSE OF ACTION (STRICT LIABILITY)

- 36. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
 - 37. At all times herein mentioned, the defendants' respective products were dangerous and

defective, in that any benefit from said products was outweighed by the serious and deadly side effects of said drugs.

- 38. Each of the defendants placed said products into the stream of commerce with reckless disregard for the public safety in that it did not carry out adequate testing, did not timely or adequately continue to test and monitor the safety of the drugs, or take other reasonable steps to assure the products were efficacious for the purpose for which they were intended without subjecting the user to significant and harmful side effects as aforesaid.
- 39. Each of the defendants are strictly liable for the harm the injured plaintiffs sustained as a result of ingesting the products as aforesaid.
- 40. As a result of reckless disregard for the public welfare and welfare of each plaintiff in particular, each of the plaintiffs is entitled to exemplary damages from each of the defendants in addition to compensatory damages sustained as a result of each of the defendants' conduct.

AS AND FOR A THIRD CAUSE OF ACTION (MISREPRESENTATION AND FAILURE TO WARN)

- 41. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 42. Beginning prior to the time the plaintiffs herein ingested the drugs as aforesaid, each of the defendants engaged in a strategy involving aggressively marketing and selling the aforesaid products by falsely misleading potential users as to the safety of the drugs, by promoting the drugs based on unsubstantiated safety claims, and by failing to protect users from serious dangers which each of the defendants knew or should have known to result from use of said products.
- 43. By use of affirmative misrepresentations and omissions, each of the defendants engaged in promotional or advertising programs that falsely and fraudulently sought to create the image and impression that the the aforesaid drugs were safe, known to be safe or had minimal risks to the public

- and each plaintiff in particular.
 - 44. Upon information and belief, each of the defendants understated downplayed or withheld information concerning health hazards and risks associated with the drugs, as well as the lack of adequate testing and monitoring for safety.
 - 45. Each of the defendants failed to provide adequate warnings and/or information concerning the harms or potential harms of and dangers of the use of said products to the public for whom the drugs were not expressly contraindicated, and diluted any warnings by representing that adverse events were not significant for persons likely to be the users of said drugs.
 - 46. As a direct and proximate result of the aforesaid failure by each of the defendants to provide appropriate warnings and/or instructions, each plaintiff sustained the harm complained of herein.
 - 47. Upon information and belief, at the times relevant to this complaint, each defendant was in possession of information demonstrating serious side effects evidencing the increased risk the drugs posed to patients, or clearly should have been in possession of such information yet continued to market the products by providing false and misleading information with regard to safety as aforesaid, and, despite the same, and despite the fact that there was existing evidence said drugs was in fact dangerous, each defendant downplayed the health hazards and risks associated with the products and in fact deceived the medical community, individual physicians and the public at large including potential users of the products by promoting the same as safe and effective.
 - 48. Upon information and belief, each defendant placed profit concerns over and above the safety of the public.
 - 49. As a result of each defendant's reckless disregard for the public welfare and welfare of each plaintiff in particular, each of the injured plaintiffs is entitled to an award of exemplary damages from each of the defendants in addition to compensatory damages sustained as a result of said conduct.

AS AND FOR A FOURTH AND SEPARATE CAUSE OF ACTION

(BREACH OF EXPRESS AND IMPLIED WARRANTIES)

- 50. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 51. Each of the defendants expressly and impliedly warranted that their aforesaid drugs were safe when used by patients for whom the drugs were not otherwise contraindicated, including the injured plaintiffs herein.
- 52. Each of the defendants breached such express and implied warranties in that their respective drugs are not safe for the purpose for which intended.
- 53. As a direct and proximate result of the aforesaid breach of express and implied warranties, each injured plaintiff is entitled to an award of compensatory and to an award of exemplary damages, inasmuch as the breach was in reckless disregard of the public health and safety.

AS AND FOR A FIFTH AND SEPARATE CAUSE OF ACTION (VIOLATION OF NEW YORK BUSINESS CORPORATION LAW § 349)

- 54. Plaintiffs incorporate by reference and reallege all preceding paragraphs as if fully set forth herein and further allege the following.
- 55. Each defendant's conduct as set forth herein constituted deceptive acts or practices and involved an extensive marketing scheme that had a broader impact on consumers at large.
- 56. Each defendant engaged in acts or practices that were deceptive or misleading in that the same were likely to mislead a reasonable consumer acting reasonably under the circumstances to ingest the products and be injured thereby.
 - 57. Each defendant's acts and practices violated New York's Business Corporation Law § 349.
- 58. The injured plaintiffs sustained harm as a direct and proximate result of the deceptive and misleading acts and practices of each of the defendants, and are entitled to compensatory and exemplary damages therefor.

RELIEF REQUESTED

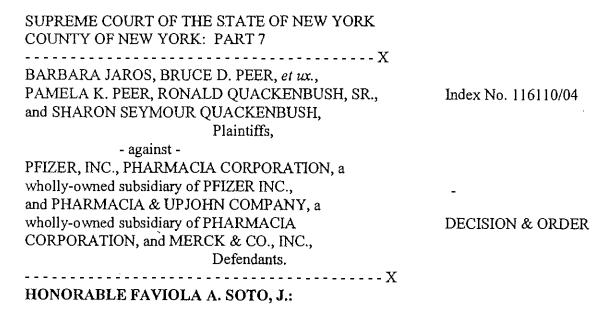
WHEREFORE, the plaintiffs demand judgment against the defendants, jointly and severally, as appropriate, on each cause of action as pled herein as follows:

- (1) Award each of the plaintiffs compensatory damages and exemplary damages against defendants on each of the first through fifth causes of action:
- (2) Award the plaintiffs such other and further relief against the defendants as the Court deems just and proper under the circumstances, including the costs and disbursements of this action.

Dated: April 7, 2005

LAW OFFICE OF RONALD R. BENJAMIN

Attorneys for Plaintiffs 126 Riverside Drive, P. O. Box 607 Binghamton, New York 13902-0607 607/772-1442



Defendants Pfizer, Inc. (Pfizer), Pharmacia Corporation (Pharmacia), and Pharmacia & Upjohn LLC s/h/a Pharmacia & Upjohn Company (Upjohn) (collectively, Pfizer defendants) move, pursuant to CPLR 3211, 3013, and 3016 (b), for dismissal of the complaint.

Plaintiffs Barbara Jaros, Bruce D. Peer, et ux., Pamela K. Peer, Ronald Quackenbush, Sr., and Sharon Seymour Quackenbush cross-move for leave to amend the complaint in the event that the motion is granted in whole or in part.

The complaint alleges as follows: Upjohn is a wholly-owned subsidiary of Pharmacia. As a result of a corporate merger between Pfizer and Pharmacia, Pfizer is responsible for the liabilities of Pharmacia and Upjohn; the Pfizer defendants are engaged in the design. manufacture, and distribution of the arthritis and acute pain medications Celebrex and Bextra. and defendant Merck is engaged in the design, manufacture, and distribution of the arthritis and acute pain medication Vioxx.

The complaint further alleges that: defendants used a wide range of marketing methods to promote these products and place them in the stream of commerce, including extensive

advertising and promotional activity that indicated that the drugs were efficacious for treatment and safe to use; defendants failed to provide adequate warnings to the medical community and the public at large about the potential harms of the drugs; as a result, plaintiffs were prescribed the drugs, and, in reliance upon the same, plaintiffs ingested the drugs as follows: Jaros ingested Vioxx, Celebrex, and Bextra; Peer ingested Vioxx and Celebrex; Ronald Quackenbush, Sr., ingested Vioxx and Bextra; and Sharon Seymour Quackenbush ingested Vioxx; each of the plaintiffs suffered severe injuries ranging from heart attacks to strokes and other conditions that are permanent in nature; had defendants carried out proper testing on their products, they would have realized the risks of using their products, including cardiovascular events such as heart attack, stroke, and thromboembolism.

The complaint contains six causes of action: (1) negligence and gross negligence; (2) strict liability; (3) misrepresentation and failure to warn; (4) breach of express and implied warranties; (5) violation of Business Corporation Law § 349; and (6) derivative spousal claims, and loss of consortium.

The Pfizer defendants argue that: (1) the complaint fails to allege how each defendant caused the asserted injuries; (2) the claims that Sharon Seymour Quackenbush asserts against them should be dismissed, because she does not allege that she ever took any products that the Pfizer defendants manufactured; (3) the "informed intermediary" doctrine bars any claims predicated upon an alleged failure to warn plaintiffs; and (4) the misrepresentation, strict products liability, breach of warranty, and General Business Law § 349 claims lack the requisite particularity, or fail to adequately allege the material elements of each claim.

The motion by the Pfizer defendants to dismiss the complaint as against them is granted

to the extent of dismissing the second, third, fourth, and fifth causes of action. The cross motion for leave to amend the complaint is denied. Plaintiffs failed to submit a copy of a proposed amended pleading or otherwise demonstrate that the proposed amended pleading has merit (see Urfirer v Cornfeld, 17 AD3d 129 [1st Dept 2005]). Without the proposed amended complaint or even a showing that an amended complaint will cure these deficiencies, the court will not exercise its discretion so as to permit an amended complaint that may bear the same or similar deficiencies, resulting in repetitive motion practice, unnecessary cost and delay to the parties and this action and an unwise allocation of judicial resources.

The first cause of action for negligence is validly stated. The complaint adequately identifies the specific drugs that each plaintiff took, the manufacturer of each drug, and that ingestion of the drugs proximately caused the injuries (heart attacks and strokes). As in any cause of action founded upon negligence, a successful plaintiff must demonstrate the existence of a duty, the breach of which may be considered the proximate cause of the damages suffered by the injured party (*Becker v Schwartz*, 46 NY2d 401, 410 [1978]). Affording plaintiffs the benefit of all favorable inferences (*Rovello v Orofino Realty Co.*, 40 NY2d 633 [1976]), the complaint pleads the essential elements of this cause of action.

The second, third, fourth, and fifth causes of action, for strict liability, misrepresentation and failure to warn, breach of express and implied warranties, and violation of Business Corporation Law § 349, respectively, are dismissed, because they consist, essentially, of conclusory allegations and are impermissibly vague, and thus, are not validly stated (*Hart v Scott*, 8 AD3d 532 [2d Dept 2004]). A complaint, replete with legal conclusions and devoid of factual allegations of the underlying wrongful conduct is not entitled to the benefit of favorable

inferences usually accorded on a pre-answer motion to dismiss (Kamhi v Tay, 244 AD2d 266 [1st Dept 1997]).

The second cause of action alleges that defendants are strictly liable for the harm that the drugs at issue caused to the plaintiffs. Although a prescription drug is by its nature an inherently unsafe product, and would, in the usual case, impute strict liability to its manufacturer, a defense is provided against such liability when the drug is properly prepared, and accompanied by proper directions and warning (*Martin v Hacker*, 83 NY2d 1, 8 [1993]). Here, the complaint contains only conclusory allegations such as "defendants' products were dangerous and defective, in that any benefit from said products was outweighed by the serious and deadly side effects of said drugs," and defendants "placed said products into the stream of commerce with reckless disregard for the public safety . . . " (Complaint, ¶ 33, 34).

As for the third cause of action for misrepresentation and failure to warn, a plaintiff must allege misrepresentation of a material fact, falsity, scienter, deception, and injury, and each with particularity (*LaSalle Natl. Bank v Ernst & Young LLP*, 285 AD2d 101 [1st Dept 2001]), which is not the case here. CPLR 3016 (b) provides:

"(b) Fraud or mistake. Where a cause of action or defense is based upon misrepresentation, fraud, mistake, wilful default, breach of trust or undue influence, the circumstances constituting the wrong shall be stated in detail."

The complaint alleges that defendants engaged in false advertising, understated the health hazards of the drugs, and failed to provide adequate warnings concerning the potential harms of the drugs, without providing any specificity as to these assertions.

As asserted by the Pfizer defendants, the "informed intermediary" doctrine is a defense to the complaint to the extent that it alleges that defendants failed to warn plaintiffs or the public at

large (Martin v Hacker, 83 NY2d at 9; Vigio v New York Hosp., 228 AD2d 278, 279 [1st Dept 1996]). The manufacturer fulfills its duty to caution against a drug's side effects by giving adequate warning through the prescribing physician, not directly to the patient (Martin v Hacker, 83 NY2d at 9). Although the complaint also alleges that defendants failed to adequately provide warnings to the medical community about side effects, these allegations are not sufficiently particular and are merely conclusory (see e.g. ¶ 43 ["defendants downplayed the health hazards and risks associated with the products and in fact deceived the medical community, individual physicians and public at large"]).

Similarly, the breach of warranty cause of action is impermissibly devoid of a factual basis (*Rose v Gelco Corp.*, 261 AD2d 381 [2d Dept 1999]). It alleges only that defendants "expressly and impliedly warranted that their aforesaid drugs were safe when used by patients for whom the drugs were not otherwise contraindicated, including the injured plaintiffs herein." In addition, plaintiffs fail to allege reliance upon the alleged express warranty with the requisite specificity (*Murrin v Ford Motor Co.*, 303 AD2d 475 [3d Dept 2003]).

The fifth cause action is for violation of the General Business Law § 349 (a) which declares as unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." To state a claim under this section, a plaintiff must allege that defendant's materially deceptive conduct caused him or her injury, and that defendant's conduct was consumer-oriented with a broad impact on consumers at large (Oswego Laborers' Local 214 Pension Fund v Marine Midland Bank, N.A., 85 NY2d 20 [1995]). Because the misrepresentation claims are insufficiently pled, this cause of action, which here is dependant upon those allegations, is similarly deficient.

The Pfizer defendants do not assert any specific challenges to the sixth cause of action for the derivative spousal claims and loss of consortium. Because this cause of action is derivative in nature, and predicated on the other causes of action (see Liff v Schildkrout, 49 NY2d 622, rearg denied sub nom, Grant v Guidotti, 49 NY2d 1048 [1980]; Paisley v Coin Device Corp., 5 AD3d 748 [2d Dept 2004]), and the negligence cause of action survives the motion to dismiss, this cause of action, too, survives. Thus, the assertion that Sharon Seymour Quackenbush has no claim against the Pfizer defendants is in error, because the complaint alleges that her husband. plaintiff Ronald Quackenbush, ingested Bextra, attributable to the Pfizer defendants.

Accordingly, it is

ORDERED that the motion by defendants Pfizer, Inc., Pharmacia Corporation, and Pharmacia & Upjohn LLC s/h/a Pharmacia & Upjohn Company defendants to dismiss the complaint is granted to the extent that the second, third, fourth, and fifth causes of action are severed and dismissed as against them; and it is further

ORDERED that the remainder of the action shall continue; and it is further ORDERED that plaintiffs' cross-motion to amend is denied; and it is further

ORDERED that defendants are directed to serve their answers to the complaint within 20 days after service of a copy of this order with notice of entry; and it is further

ORDERED that all parties shall appear for a preliminary conference on July 28, 2005, promptly at 9:30 a.m., 111 Centre Street, Room 949; and it is further

ORDERED that movants shall serve a copy of this decision and order upon the County Clerk and the Trial Support Office within thirty days of entry.

Dated: New York, New York June 23, 2005

Copies mailed

<u>AFFIDAVIT OF SERVICE</u>

STATE OF NEW YORK) SS.: COUNTY OF NEW YORK

Nicole L. Wilson, being duly sworn, deposes and says: I am over the age of 18 years old and not a party to this action. On the 20th day of July, 2005, I caused to be served true copies of the foregoing Pfizer DEFENDANTS' NOTICE OF MOTION, MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS, and AFFIRMATION OF STEPHEN P. McLAUGHLIN in support thereof on all counsel by mail at the following addresses:

> Ronald R. Benjamin, Esq. LAW OFFICES OF RONALD R. BENJAMIN 126 Riverside Drive P.O. Box 607 Binghamton, New York 13902-0607

Vilia B. Hughes, Esq. HUGHES HUBBARD & REED, LLP One Battery Park Plaza New York, New York 10004

the addresses designated by said attorneys for that purpose. Service was completed by depositing true copies of same enclosed in postpaid properly addressed wrappers, in an official depository under the exclusive care and custody of the United States Postal Service.

Sworn to before me this 20th day of July, 2005

RACHEL MARIN Notary Public, State of New York No. 01MA6124170 Qualified in New York County Commission Expires March 21, 2009 SUPREME COURT OF THE STATE OF NEW YORK - NEW YORK COUNTY V MEDNED KADMORIAM

PRESENT: SHIRLEY WERNER RORIVALION J.S.C.		PART <u>5</u>
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· v ·	MOTION SEQ. NO.	01
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The following papers, numbered 1 to were read on this	motion to/for	
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Answering Affidavits — ExhibitsReplying Affidavits		
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FOR THE FOLLOWING REASON(S):

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE



DLA Piper Rudnick Gray Cary US LLP

The Marbury Building 6225 Smith Avenue Baltimore, Maryland 21209-3600 T 410.580.3000 F 410.580.3001 W www.dlapiper.com

T. BRENDAN KENNEDY brendan.kennedy@dlapiper.com T 410.580.4196 F 410.580.3196

June 11, 2005

Document 9

Ronald R. Benjamin, Esquire Law Offices of Ronald R. Benjamin 126 Riverside Drive P.O. Box 607 Binghmaton, New York 13902-0607

JUN NEW YORK COUNTY CLERK'S OFFICE

Helen Bilik, et al. v. Pfizer, Inc., et al., Index No. 106237/05 Re:

Dear Mr. Benjamin:

I represent Pfizer Inc., Pharmacia Corp., and Pharmacia & Upjohn Co. ("Pfizer Defendants") in the above-referenced matter. Through this letter, I consent to service by mail on the Pfizer Defendants pursuant to N.Y. C.P.L.R. §312-a. Accordingly, the Pfizer Defendants must answer or otherwise respond to the Complaint on or before June 30, 2005.

If you have any questions, please feel free to contact me.

Sincerely.

T. Brendan Kennedy

/tbk

COUNTY CLERK, NEW YORK COUNTY

Application for INDEX NUMBER pursuant to Section 8018, C.P.L.R.

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INDEX	NUMBER

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TITLE	OF	ACTION	OR	PRO	CEEDING
	VI.	ACTION	VN	rnv	OEEDII10

Helen Bilik, Elizabeth Boone, Mary J. Mahar, Carolyn S. Croft, Geraldine M. Alapeck, Dean Santacrose, and Stasisa Simmons,

Plaintiffs,

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Pfizer, Inc., Pharmacia Corporation, a wholly-owned subsidiary of Pfizer, Inc., and Pharmacia & Upjohn Company, a wholly-owned subsidiary of Pharmacia Corporation, and Merck & Co., Inc.,

Defendants.

 C	HECK ONE	
COMMERCIAL ACTION		NOT COMMERCIAL ACTION
CONSUMER CREDIT TRANSACTION		NOT CONSUMER CREDIT TRANSACTION
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IF THIRD PARTY ACTION MAIN INDEX NO.

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	orney for Plaintiff Law Office & Korale Der Janen
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Tele	ephone No. Buxchan for Ny 15902 607-772-1
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Atte	orney for Defendant
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A.	Nature and object of action or Negli Cexco
	Nature of special proceeding
В.	Application for Index Number filed by: Plaintiff Defendant
C.	Was a previous Third Party Action filed Yes No Date filed

SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE, and STASIA SIMMONS,

Plaintiff,

-against-

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., PHARMACIA & UPJOHN COMPANY, a wholly-owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO., INC.,

Defendant.

INDEX NO.: 106237/05

AFFIDAVIT OF SERVICE

STATE OF NEW YORK)

: ss.:

COUNTY OF NEW YORK

Jordana M. Meltzer, being duly sworn, deposes and says that I am over the age of eighteen years, not a party to this action, and am in the employ of Hughes Hubbard & Reed, LLP, attorneys for defendant MERCK & CO., INC. herein; that on May 26, 2005 at approximately 10:30 a.m., she served the attached ACKNOWLEDGMENT OF RECEIPT BY MAIL OF SUMMONS AND COMPLAINT by first class mail of the same aforementioned document, true copies being in securely enclosed, postpaid wrappers, and depositing same in a depository under the exclusive care and control of the United States Government at One Battery Park Plaza, within the city, county and state of New York, properly addressed as follows:

Ronald R. Benjamin, Esq. 126 Riverside Drive P.O. Box 607 Binghamton, New York 13902-0607

> - ordana Melt Jordana Meltzer

Sworn to before me on this 26th of May, 2005.

Notary Public

PATRICIA E. SMITH
Notary Public, State of New York
No. 1SM4796951
Qualified in Richmond County
Certificate Filed in New York County
Commission Expires March 30, 20

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131116, 1	MOTION DATE
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The following papers, numbered 1 to were read	on this motion to/for
Notice of Motion/ Order to Show Cause — Affidavits —	PAPERS NUMBERE
Answering Affidavits — Exhibits	
Replying Affidavits	
Cross-Motion: Yes No	
Upon the foregoing papers, it is ordered that this motion	is withdrawn.

REFERENCE

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J.S.C.

NON-FINAL DISPOSITION

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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

HELEN BILIK, ELIZABETH BOONE, MARY J. MAHAR, CAROLYN S. CROFT, GERALDINE M. ALAPECK, DEAN SANTACROSE and STASIA SIMMONS.

Index No. 106237/05

Plaintiffs,

-against-

PFIZER, INC., PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC., and PHARMACIA & UPJOHN COMPANY, a wholly owned subsidiary of PHARMACIA CORPORATION, and MERCK & CO. INC.,

Defendants.



MEMORANDUM OF LAW OF DEFENDANTS PFIZER, INC., PHARMACIA CORPORATION, AND PHARMACIA & UPJOHN LLC IN SUPPORT OF THEIR MOTION TO DISMISS

> DLA PIPER RUDNICK GRAY CARY US LLP 1251 Avenue of the Americas New York, New York 10020 (212) 835-6000 Attorneys for Pfizer Defendants

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N.Y. C.P.L.R. (McKinney 2004) § 3211(a)(7)
N.Y. Gen. Bus. Law § 349 (McKinney 2004)

Defendants Pfizer, Inc., Pharmacia Corporation, and Pharmacia & Upjohn LLC (collectively "Pfizer Defendants"), by their counsel DLA Piper Rudnick Gray Cary US LLP, respectfully submit this Memorandum of Law in support of their Motion to Dismiss all causes of action asserted in Plaintiffs' Complaint (the "Complaint") pursuant to Rule 3211 of New York's Civil Practice Law and Rules.

PRELIMINARY STATEMENT

This is a products liability case involving three prescription drugs: Celebrex and Bextra, which are manufactured and distributed by Pfizer, Inc., and Vioxx, which was manufactured and distributed by Defendant Merck & Co., Inc. ("Merck"). Plaintiffs are seven allegedly injured patients who were prescribed Celebrex, Bextra and/or Vioxx. Plaintiffs claim that after taking Celebrex, Bextra and/or Vioxx, each suffered injuries.

Pfizer Defendants submit this Memorandum of Law in support of their motion for an order, pursuant to CPLR 3211(a)(7), 3013 and 3016(b), dismissing causes of action and striking specific allegations in Plaintiffs' Complaint. Pfizer Defendants seek dismissal for the following reasons:

- (1) by merely alleging wrongdoing by all Defendants, without distinguishing among them, Plaintiffs do not satisfy their obligation to plead facts demonstrating how each Defendant caused injury to Plaintiffs;
- (2) the "informed intermediary" doctrine bars Plaintiffs' Negligence, Gross Negligence, Misrepresentation, Failure to Warn and Breach of Express or Implied Warranties causes of action to the extent they are predicated on a duty to warn Plaintiffs;
- (3) Plaintiffs' Misrepresentation claim should also be dismissed because the Complaint fails to allege the circumstances surrounding the alleged wrongs with the particularity required by CPLR 3016(b);

- (4) Plaintiffs' Strict Product Liability Design or Manufacturing Defect and Breach of Warranty causes of action should be dismissed because the Complaint fails to allege facts sufficient to establish the material elements of each claim; and
- (5) Plaintiffs' claim that Pfizer Defendants violated General Business Law § 349 should be dismissed because Plaintiffs fail to plead adequately the elements of the claim.

STATEMENT OF FACTS

According to the Complaint, Plaintiff Helen Bilik "ingested the drugs Vioxx and Celebrex as directed by her physicians." Compl. ¶ 15. Plaintiff Elizabeth Boone "ingested the drugs Vioxx, Bextra and Celebrex as directed by her physicians." Compl. ¶ 16. Plaintiff Mary J. Mahar "ingested the drugs Vioxx and Bextra as directed by her physicians." Compl. ¶ 17. Plaintiff Carolyn S. Croft "ingested the drugs Celebrex and Vioxx as directed by her physicians." Compl. ¶ 18. Plaintiff Geraldine M. Alapeck "ingested the drugs Vioxx and Bextra at the direction of her physicians." Compl. ¶ 19. Plaintiff Dean Santacrose "ingested the drugs Vioxx and Celebrex at the direction of his physicians." Compl. ¶ 20. Plaintiff Stasia Simmons "ingested the drugs Vioxx and Bextra at the direction of her physicians." Compl. ¶ 21. Plaintiffs allege that they each "sustained severe injuries, which, upon information and belief, are permanent in nature" after taking the drugs. Compl. ¶ 23.

Plaintiffs further claim that Defendants misled users and consumers of Celebrex, Bextra and Vioxx, and "failed to provide adequate warnings and/or information concerning" the potential serious dangers that might result from use of the products, and "diluted any warnings by representing that adverse events were not significant for persons likely to be users of Celebrex, Bextra and Vioxx. Compl. ¶ 45.

According to Plaintiffs, Defendants misled potential users by engaging "in extensive advertising and promotional activity which indicated their drugs were efficacious for treating and

that it was safe to use, and published a description of their respective drugs in the Physician's Desk Reference for use by doctors in determining whether to prescribe said drugs to patients." Compl. ¶ 10.

Plaintiffs also allege that Defendants "engaged in intentional efforts to hide and withhold from the public safety concerns" about Celebrex, Bextra and Vioxx, Compl. ¶ 13. Plaintiffs claim "that despite the fact that there was existing evidence said drugs [were] in fact dangerous," Defendants "downplayed the health hazards and risks associated with the products and in fact deceived the medical community, individual physicians and the public at large including potential users of the products by promoting the same as safe and effective." Compl. ¶ 47. At the same time, however, Plaintiffs allege that Defendants "did not carry out adequate testing, [and] did not timely or adequately continue to test and monitor the safety of the drugs." Compl. ¶ 38.

Additionally, Plaintiffs claim that "any benefit from said products was outweighed by the serious and deadly side effects of said drugs." Compl. ¶ 37.

The Complaint asserts five causes of action based on these allegations: (1) Negligence and Gross Negligence; (2) Strict Product Liability Design or Manufacturing Defect; (3) Misrepresentation and Failure to Warn; (4) Breach of Implied and Express Warranties; and (5) violation of General Business Law § 349. Compl. ¶¶ 29-58.

ARGUMENT

As demonstrated below, all nine of Plaintiffs' causes of action have fatal flaws requiring their dismissal in whole or in part. Notably, this Complaint contains references to causes of

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Plaintiffs set forth five causes of action in their Complaint (Compl. ¶¶ 24-57), but they actually allege nine theories of recovery. This Memorandum of Law treats each theory of recovery as a distinct cause of action, and addresses them in the order they are raised in the Complaint.

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action that are substantially similar to those asserted in numerous complaints recently filed by various plaintiffs' attorneys in New York County, and Justice Faviola A. Soto recently issued a six-page decision and order dismissing in large part the first of these complaints. See Decision and Order Granting Defs.' Mot. to Dismiss, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004). In addition, several of Plaintiffs' claims must be dismissed because they rely on bare legal conclusions rather than factual allegations. See Brown v. Albert Einstein Coll. of Med. of Yeshiva Univ., 172 A.D.2d 197, 198, 568 N.Y.S.2d 61, 62 (1st Dep't 1991) ("While factual averments of a complaint must be taken as true on a motion to dismiss for legal insufficiency, a pleader's bare legal conclusions need not.").

I. The Court Should Follow Justice Soto's Decision And Order In <u>Jaros</u> And Dismiss The Instant Complaint Under CPLR 3211, 3013 And 3016(b)

The <u>Jaros</u> case was commenced in the Supreme Court of the State of New York for the County of New York by a complaint that is substantially similar to the Complaint herein, alleging similar injuries from the same allegedly wrongful practices of the same defendant. By recent decision, Justice Soto dismissed all substantive causes of action alleged by <u>Jaros</u> plaintiffs – the strict liability, misrepresentation, failure to warn, express and implied warranty, and Gen. Bus. Corp. Law § 349 – save one (negligence). <u>See McLaughlin Aff.</u>, Ex. B. Justice Soto found that, other than the negligence cause of action, the patient-plaintiffs in that case failed to plead facts sufficient to support the causes of action alleged in the complaint.

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Justice Soto dismissed the strict liability, misrepresentation and failure to warn, breach of express and implied warranties, and violation of Gen. Bus. Corp. Law § 349 claims. A true and correct copy of the Decision and Order of the Honorable Faviola A. Soto in <u>Jaros</u> is attached to the Affirmation of Stephen P. McLaughlin as Ex. B.

The Complaint herein is likewise insufficiently pled. As explained in detail below, each purported cause of action is supported not by well-pled factual allegations, but by mere conclusory allegations and legal conclusions. "A complaint, replete with legal conclusions and devoid of factual allegations of the underlying wrongful conduct is not entitled to the benefit of favorable inferences usually accorded on a pre-answer motion to dismiss." Decision and Order Granting Defs.' Mot. Dismiss at 3-4, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) (citing Kamhi v. Tay, 244 A.D.2d 266, 664 N.Y.S.2d 288 (Ist Dep't 1997)). Because, just as in Jaros, the causes of actions contained in the Complaint are supported by mere conclusory allegations and legal conclusions, the Complaint should be dismissed.

II. Plaintiffs Fail To Allege How Each Defendant Caused The Asserted Injuries

Dismissal of a claim pursuant to CPLR 3211(a)(7) is required where a plaintiff cannot succeed upon any reasonable view of the facts stated. Campaign for Fiscal Equity, Inc. v. State, 86 N.Y.2d 307, 318, 631 N.Y.S.2d 565, 571 (1995). Thus, a complaint will be dismissed where multiple "causes of action are pleaded against all defendants collectively without any specification as to the precise tortious conduct charged to a particular defendant." Aetna Cas. & Sur. Co. v. Merchs. Mut. Ins. Co., 84 A.D.2d 736, 737, 444 N.Y.S.2d 79, 80 (1st Dep't 1981).

In order to recover under each of the causes of action alleged in the complaint, a plaintiff must plead and prove a causal link between the injury complained of and the actions of each defendant. See, e.g., Amatulli by Amatulli v. Delhi Const. Corp., 77 N.Y.2d 525, 532, 569 N.Y.S.2d 337, 341 (1991) ("For there to be recovery for injuries or damages . . . by a defective product . . . that defect must have been a substantial factor in bringing about the injury"); Pappas v. Harrow Stores, Inc., 140 A.D.2d 501, 504, 528 N.Y.S.2d 404, 407 (2d Dep't 1988)

("the negligence on which the plaintiff relies must be a proximate cause of the injury for which he or she seeks recovery").

Here, Plaintiffs fail to allege the precise tortious conduct of each Defendant. The Complaint also is deficient because it fails to identify any causal link between Defendants' products and Plaintiffs' alleged injuries. Plaintiffs only vaguely allege use of two or three different products. See, e.g., Compl. ¶¶ 15-21 ("[The] injured plaintiff Helen Bilik ingested the drugs Vioxx and Celebrex as directed by her physicians"). Plaintiffs do not identify, however, which product caused their harm. Because Plaintiffs have failed to allege how each Defendant caused the asserted injuries, all nine causes of action in the Complaint should be dismissed. See Cresser v. Am. Tobacco Co., 174 Misc. 2d 1, 2, 662 N.Y.S.2d 374, 375 (Sup. Ct. Kings Co. 1997) (dismissing complaints where plaintiffs failed to "plead facts demonstrating how each one of the defendants themselves caused injury to plaintiffs").

III. The "Informed Intermediary" Doctrine Precludes Negligence, Gross Negligence, Misrepresentation, Failure To Warn And Breach Of Express Or Implied Warranties Causes Of Action To The Extent They Are Predicated On A Duty To Warn The Patient Or The General Public

Manufacturers of prescription drugs have a duty to warn only prescribing physicians, not particular patients or the public at large:

Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an "informed intermediary" between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.

Martin v. Hacker, 83 N.Y.2d 1, 9, 607 N.Y.S.2d 598, 601 (1993) (citations omitted); see also Glucksman v. Halsey Drug Co. Inc., 160 A.D.2d 305, 307, 553 N.Y.S.2d 724, 726 (1st Dep't

1990) ("the manufacturer's duty [to warn] is owed to the medical community, and not the patient").

The "informed intermediary" doctrine is, therefore, a complete defense to failure to warn claims, to the extent such claims are predicated on a failure to warn the patient or the public at large. See, e.g., Martin v. Hacker, 185 A.D.2d 553, 554-55, 586 N.Y.S.2d 407, 409 (3d Dep't 1992), aff'd, 83 N.Y.2d 1, 607 N.Y.S.2d 598 (1993).

Moreover, the "descriptive terminology used to denominate the cause of action" is irrelevant and any claims that are predicated on a duty to warn the patient or the public should be dismissed as a matter of law under the "informed intermediary" doctrine. Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61-62, 423 N.Y.S.2d 95, 97 (4th Dep't 1979) (dismissing strict liability and breach of warranty causes of action under the informed intermediary doctrine), aff'd, 52 N.Y.2d 768, 436 N.Y.S.2d 614 (1980); see also Martin, 83 N.Y.2d at 9 n.1, 607 N.Y.S.2d at 601 n.1 ("Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent."); Decision and Order Granting Defs.' Mot. Dismiss at 4-5, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) ("As asserted by the Pfizer defendants, the 'informed intermediary' doctrine is a defense to the complaint to the extent that it alleges that defendants failed to warn plaintiffs or the public at large. The manufacturer fulfils its duty to caution against a drug's side effects by giving adequate warning through the prescribing physician, not directly to the patient.") (citations omitted).

Thus, because the learned intermediary doctrine is a complete legal defense against claims based upon an alleged failure to warn the patient or the public about the side effects of prescription drugs, courts regularly dismiss such claims as a matter of law. See, e.g., Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (granting motion for judgment

on the pleadings, the court ruled that "Searle had no duty to warn anyone other than [plaintiff's] prescribing doctor about the potential dangers of Celebrex, and [plaintiff's] failure to warn claim is dismissed except as related to [plaintiff's] prescribing physician"); In re Rezulin Prods. Liab. Litig., No. 00 Civ. 2843, 2003 WL 21285535 at *1 (S.D.N.Y. June 3, 2003) ("The complaint fails to state a legally sufficient claim against these defendants in view of the learned intermediary doctrine."); In re Baycol Prods. Litig., No. 1431, Civ. 03-4954, 2004 WL 1118642, at *4-5 (D. Minn. May 17, 2004) (granting motion to dismiss under "learned intermediary doctrine" where "thrust of Complaint is that [pharmaceutical defendants] failed to inform the public that [the drug] was dangerous").

Despite the well-established law that Pfizer Defendants' duty to warn is limited to physicians, the Complaint is replete with allegations that Defendants failed to warn the public and Plaintiffs of the alleged risks associated with their products. Indeed, six of Plaintiffs' nine causes of action hinge in large part on such allegations.

Thus, the Failure to Warn cause of action is based in part on the claims that Defendants "failed to provide adequate warnings and/or information concerning the harms or potential harms of and dangers of the use of said products to the public." Compl. ¶ 45. Similarly, the Misrepresentation cause of action is based in part on the allegation that Defendants deceived "the public at large including potential users of the products by promoting the same as safe and effective" despite known dangers. Compl. ¶ 47.

The Negligence and Gross Negligence causes of action also are based in part on the claims that Defendants "evinced a reckless disregard for the safety of persons who would be using said products by downplaying, minimizing, and otherwise failing to warn . . . the public in general and each plaintiff in particular about the serious and deadly side effects of their products." Compl. ¶ 33.

Finally, the Breach of Express and Implied Warranty cause of action is necessarily "dependent upon an assessment of the adequacy of the warning or precautions provided by the manufacturer to the medical community." Wolfgruber, 72 A.D.2d at 60, 423 N.Y.S.2d at 96 (dismissing breach of warranty claims under the informed intermediary doctrine).

Thus, the Negligence, Gross Negligence, Misrepresentation, Failure to Warn and Breach of Express and Implied Warranty causes of action should be dismissed to the extent they are predicated on Pfizer Defendants' alleged duty to warn Plaintiffs or the general public.³

IV. Plaintiffs Fail To State Their Negligent Misrepresentation Claim With The Particularity Required by CPLR 3016(b)

When a complaint asserts a cause of action for misrepresentation, "the circumstances constituting the wrong shall be stated in detail." N.Y. C.P.L.R. 3016(b) (McKinney 2004). To avoid dismissal under CPLR 3016(b), a plaintiff must also plead specific and detailed facts supporting each element of her claim. See Schneider v. Hand, 296 A.D.2d 454, 454, 744 N.Y.S.2d 899, 900 (2d Dep't 2002) (dismissing negligent misrepresentation claim for failure to plead with particularity under CPLR 3016(b)); Stan Winston Creatures, Inc. v. Toys "R" Us, Inc., No. 604183/02, 2004 WL 1949071, at *5 (Sup. Ct. New York County Sept. 1, 2004) ("CPLR 3016(b) also requires negligent misrepresentation claims to be pleaded in sufficient detail."); see also Decision and Order Granting Defs.' Mot. Dismiss at 4, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) ("a plaintiff must allege misrepresentation of a material fact, falsity, scienter, deception, and injury, and each with particularity").

In <u>Martin</u>, the plaintiff alleged that the drug manufacturer breached "their duties to adequately warn both the medical profession and the ultimate user of the medications' adverse side effects. ... Supreme Court granted [defendant's] motion to the extent of dismissing plaintiff's ... causes of action that alleged failure to warn the ultimate user." 83 N.Y.2d at 8-9; 607 N.Y.S.2d at 600-01 (emphasis in original). The trial court's dismissal of plaintiff's claims of failure to warn the end user were not addressed on appeal by either the Appellate Division or the Court of Appeals.

It is, thus, not sufficient to plead misrepresentation in conclusory terms. See Tarzia v. Brookhaven Nat'l Lab., 247 A.D.2d 605, 605, 669 N.Y.S.2d 230, 231 (2d Dep't 1998) ("The plaintiffs' bare assertion that the defendants 'negligently misrepresented to the plaintiffs the risk created by use, discharge and deposit of the hazardous materials' is legally insufficient to state a cause of action for negligent misrepresentation."). Rather, a plaintiff must "allege with specificity the contents of the allegedly false representation," Andre Strishak & Associates, P.C. v. Hewlett Packard Company, 300 A.D.2d 608, 610, 752 N.Y.S.2d 400, 403 (2d Dep't 2002), and "furnish sufficient examples of misrepresentations" on which he or she relied. Small v. Lorillard Tobacco Co., 252 A.D.2d 1, 15, 679 N.Y.S.2d 593, 604 (1st Dep't 1998), aff'd, 94 N.Y.2d 43, 698 N.Y.S.2d 615 (1999).

In addition, a plaintiff must plead in detail the circumstances surrounding the alleged misrepresentation of a material fact, including the person who made the representation and when, where and to whom it was made. See EBC I, Inc. v. Goldman Sachs & Co., 7 A.D.3d 418, 420, 777 N.Y.S.2d 440, 443 (1st Dep't 2004) ("At the least, plaintiff should have identified the person(s) who made [the] misrepresentation, and, to that end, the motion court correctly dismissed the fraud claim"); Eastman Kodak Co. v. Roopak Enters., Ltd., 202 A.D.2d 220, 222, 608 N.Y.S.2d 445, 446 (1st Dep't 1994) (dismissing counter-claim where "defendant alleged neither the time nor the place of the purported misrepresentations nor which employee of the plaintiff purportedly made them"); Schneider, 296 A.D.2d at 454, 744 N.Y.S.2d at 900 (dismissing negligent misrepresentation cause of action where "plaintiff failed to allege with specificity" how defendant made a false statement and how plaintiff was injured).

Here, the Complaint contains only vague, conclusory averments with respect to the alleged misrepresentations, such as that Defendants "downplayed the health hazards and risks associated with the products." Compl. ¶ 47. It does not allege any specific and detailed facts

regarding the substance of what was said, who said it, when the alleged misrepresentation was made, or where it was made.

Courts have held that similar allegations in other pharmaceutical products liability actions were insufficient under nearly identical federal pleading standards. See In re Rezulin Prods. Liab. Litig., 133 F. Supp. 2d 272, 285 (S.D.N.Y. 2001) (declaring insufficient plaintiff's conclusory allegations that defendants "knew, or should have known, that dangerous risks were associated with the use of [Rezulin]" but that despite this knowledge they "consciously ignored and understated the health risks associated with Rezulin" and participated in producing advertisements and promotions that "contained misrepresentations and omissions of fact that were intended to create in the minds of the consuming public the false sense and feeling that [Rezulin] was safe"); Blackmon v. Am. Home Prods. Corp., 328 F. Supp. 2d 659, 667-68 (S.D. Tex. 2004) (declaring insufficient plaintiff's conclusory allegations that "Defendants . . . knowingly or recklessly made false, material representations by withholding and/or concealing information from the FDA, consumers and the general public"); Hernandez v. CIBA-GEIGY Corp. et al., 200 F.R.D. 285, 290-91, (S.D. Tex. 2001) (declaring insufficient plaintiff's conclusory allegations that "Novartis failed to warn them that the full range of side effects of Ritalin had not been adequately studied, . . . that Novartis failed to disclose the limited effectiveness of its product and [that Novartis] misled clinicians and the public to believe that Ritalin would improve academic performance").

Likewise, here, Plaintiffs' Complaint does not satisfy the applicable pleading requirements, thus warranting a dismissal of their Misrepresentation cause of action.

V. Plaintiffs' Design And/Or Manufacturing Defect And Breach Of Warranty Causes Of Action Should Be Dismissed Because The Complaint Fails To Allege Facts Sufficient To Establish The Material Elements Of Each Claim

Section 3013 of CPLR requires that causes of action asserted in a complaint be pled with sufficient particularity:

Statements in a pleading shall be sufficiently particular to give the court and parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the *material elements of each cause of action* or defense.

CPLR 3013 (emphasis added). To meet this requirement, a plaintiff must plead facts, not conclusions. Slotnick v. RBL Agency Ltd., 271 A.D.2d 365, 366, 706 N.Y.S.2d 431, 432 (1st Dep't 2000); Foley v. D'Agostino, 21 A.D.2d 60, 63, 248 N.Y.S.2d 121, 125 (1st Dep't 1964).; Decision and Order Granting Defs.' Mot. Dismiss at 3, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) (plaintiffs' causes of action for Strict Liability and Breach of Warranty were dismissed because "they consist, essentially, of conclusory allegations and are impermissibly vague, and thus are not validly stated.").

A. Design Defect

In New York, a "design defect" refers to a flaw inherent in the design of a product. Denny v. Ford Motor Co., 87 N.Y.2d 248, 258 n.3, 639 N.Y.S.2d 250, 256 n.3 (1995). To state a claim for design defect, a plaintiff must plead facts sufficient to demonstrate a defect in the product's design that renders the product "not reasonably safe" because it creates a risk to consumers that outweighs the product's utility, and the existence of a safer alternative design for the product. Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 107, 463 N.Y.S.2d 398, 402 (1983).

Complaints that do not plead sufficiently particular facts for each of these elements are subject to dismissal. See Forni v. Ferguson, 232 A.D.2d 176, 176, 648 N.Y.S.2d 73, 73 (1st Dep't 1996) (failure to plead existence of a legally cognizable defect); Sabater ex rel. Santana v. Lead Indus. Ass'n, 183 Misc. 2d 759, 765, 704 N.Y.S.2d 800, 804 (Sup. Ct. Bronx County 2000) (failure to allege a safer alternative design). "[M]erely alleging that a product is inherently dangerous is insufficient to establish a design defect." Id.

The Complaint here fails to allege any specific facts supporting the material elements of a design defect claim. First, nowhere in the Complaint do Plaintiffs identify a specific defect. Instead, the Complaint contains only vague statements that Celebrex and Bextra are "dangerous and defective." Compl. ¶ 37. Second, Plaintiffs fail to plead any facts showing that Celebrex and Bextra are "not reasonably safe" or that their risks outweigh their utility. Again, Plaintiffs' only effort to meet this requirement is a conclusory statement that "any benefit from said products was outweighed by the serious and deadly side effects of said drugs." Compl. ¶ 37. Finally, Plaintiffs fail to allege any facts with respect to the existence of a safer alternative design. These vague, general assertions and legal conclusions fail to provide any factual support for Plaintiffs' claim and fail to put Pfizer Defendants and the Court on notice of Plaintiffs' claims as required by CPLR 3013. Accordingly, Plaintiffs' design defect claim should be dismissed.

B. Manufacturing Defect

A manufacturing defect refers to "some flaw in the fabrication process." Denny, 87 N.Y.2d at 257-58 n.3, 639 N.Y.S.2d at 255-56 n.3. To establish a manufacturing defect claim, a plaintiff must show that "the product was defective when it left the hands of the manufacturer" due to "a mistake in manufacturing." Rosado v. Proctor & Schwartz, Inc., 66 N.Y.2d 21, 25, 494 N.Y.S.2d 851, 854 (1985); Robinson v. Reed-Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 478, 426 N.Y.S.2d 717, 720 (1980).

The Complaint here does not contain any factual allegations that would support a manufacturing defect claim. The Complaint does not identify what the alleged defect was or provide any facts to suggest that Celebrex and Bextra were not manufactured as intended. Plaintiffs' manufacturing defect claim should, therefore, be dismissed, as well.

C. Breach Of Express Warranty

To avoid dismissal of a breach of express warranty claim, a complaint must identify specific representations constituting the alleged warranty. See Bichler v. Willing, 58 A.D.2d 331, 332, 397 N.Y.S.2d 57, 58 (1st Dep't 1977) (dismissing breach of express warranty claim for prescription medicine where plaintiff provided only "imprecise conclusory allegations" as to pharmacist's representations regarding "safety or side effects" of drug; "[t]hus, there is no basis on which recovery can be allowed for breach of an express warranty"); Copeland v. Weyerhauser Co., 124 A.D.2d 998, 998, 509 N.Y.S.2d 227, 228 (4th Dep't 1986) ("The proposed cause of action for breach of express warranty is insufficient because of failure to set forth the terms of the warranty upon which plaintiffs rely.").

CPLR 3013 also requires Plaintiffs to allege facts showing reliance on the alleged warranty. See Murrin v. Ford Motor Co., 303 A.D.2d 475, 477, 756 N.Y.S.2d 596, 597 (2d Dep't 2003) ("the plaintiff failed to allege that he understood that the [defendant's] advertisements . . . were part of the bargain or that he even was aware of these advertisements before his purchase"); Wojcik v. Empire Forklift, Inc., 14 A.D. 3d 63, 65-66, 783 N.Y.S.2d 698, 700 (3d Dep't 2004) ("Inasmuch as plaintiffs failed to establish that the promotional literature was 'part of the bargain' . . . [they] failed to allege an essential element of the formation of an express warranty.") (quoting Murrin, 303 A.D.2d at 477, 756 N.Y.S.2d at 597).

The Complaint here contains only conclusory allegations that Defendants "expressly and impliedly warranted that their aforesaid drugs were safe when used by patients for whom the

drugs were not otherwise contraindicated, including the injured plaintiffs herein." Compl. ¶ 51.

The Complaint contains no factual allegations identifying any specific express warranties made by Pfizer Defendants or stating when, where, and to whom these alleged warranties were made.

The Complaint contains similarly conclusory allegations regarding reliance on alleged, unidentified misrepresentations. See, e.g., Compl. ¶ 51-53. The Complaint contains no allegations that Plaintiffs actually saw or heard any representation from Pfizer Defendants about Celebrex or Bextra or that such representations were "part of the bargain." When faced with the identical allegation in a similar case, Judge Soto dismissed plaintiffs' breach of warranty claim, finding it "impermissibly devoid of factual basis." Decision and Order Granting Defs.' Mot. Dismiss at 5, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004). Dismissing the claim, Judge Soto explained, "[Plaintiff's breach of warranty cause of action] alleges only that defendants 'expressly and impliedly warranted that their aforesaid drugs were safe when used by patients for whom the drugs were not otherwise contraindicated, including the injured plaintiffs herein.'" Id.

Thus, the Complaint fails to state a cause of action for breach of express warranty because it lacks the factual basis required under CPLR 3013.

D. Breach Of Implied Warranty

To plead a cause of action for breach of implied warranty, a plaintiff must allege that the product was defective and that it was unfit for the purposes intended. Denny, 87 N.Y.2d at 258-262, 639 N.Y.S.2d at 256-58. A complaint that fails to allege "any particular defect upon which the breach of warranty claim may be predicated" does not state a breach of warranty claim. Travelers Ins. Co. v. Ferco, Inc., 122 A.D.2d 718, 719, 511 N.Y.S.2d 594, 595 (1st Dep't 1986). "Pleadings which are so devoid of factual substance require dismissal pursuant to CPLR § 3211(a)(7)." Id.; see also Decision and Order Granting Defs.' Mot. Dismiss at 5, June 23, 2005,

Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) (breach of warranty cause of action dismissed because it was "impermissibly devoid of a factual basis").

Here, Plaintiffs do not identify any specific defect in Celebrex or Bextra or offer any factual allegations to establish the existence of a defect. See Section V. A, supra. Nor do Plaintiffs allege any facts showing that Celebrex or Bextra were not safe or fit for their intended use. Without any factual support, Plaintiffs' conclusory allegations are not sufficient to state a cause of action for breach of implied warranty.

VI. Plaintiffs Fail To Adequately Plead A Cause Of Action Under General Business Law § 349

General Business Law § 349 bars "deceptive acts or practices in the conduct of any business." N.Y. Gen. Bus. Law § 349 (McKinney 2004). "A plaintiff under Section 349 must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act." Stutman v. Chemical Bank, 95 N.Y.2d 24, 29, 709 N.Y.S.2d 892, 895 (2000).

For a Section 349 cause of action to survive a motion to dismiss, the complaint must provide factual allegations supporting each element of the claim. Thus, New York courts routinely dismiss complaints that fail to identify statements constituting a deceptive act or practice. See Decision and Order Granting Defs. Mot. Dismiss at 5, June 23, 2005, Barbara Jaros, et al. v. Pfizer, Inc., et al., No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) ("[b]ecause the misrepresentation claims are insufficiently pled, [the General Business Law § 349] cause of action, which here is dependent upon those allegations" was dismissed); see also Kamhi, 244 A.D.2d at 266, 664 N.Y.S.2d at 290 (dismissing Section 349 claim where complaint

was "replete with legal conclusions and devoid of any factual allegation of the underlying wrongful conduct for which plaintiff seeks to hold defendants . . . liable"); see also Small, 94 N.Y.2d at 56, 698 N.Y.S.2d at 620-621 (dismissing Section 349 claim where the complaint contained only conclusory assertions that "consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury under General Business Law § 349.").

Courts also dismiss Section 349 claims where the plaintiff fails to plead sufficient facts to show causation:

Although the plaintiff cites particular misleading statements by [defendant] regarding the reliability of [its product], he nowhere states in his complaint that he saw any of these statements before he purchased or came into possession of his [product]. If the plaintiff did not see any of these statements, they could not have been the cause of his injury, there being no connection between the deceptive act and the plaintiff's injury.

Gale v. Int'l Bus. Mach. Corp., 9 A.D.3d 446, 447, 781 N.Y.S.2d 45 (2d Dep't 2004).

The Complaint here fails to identify any statement or representation by Pfizer Defendants, which allegedly constitutes a deceptive act or practice under General Business Law § 349. In addition, "because the misrepresentation claims are insufficiently pled, this cause of action, which here is dependent upon those allegations, is similarly deficient." Decision and Order Granting Defs.' Mot. Dismiss at 5, June 23, 2005, <u>Barbara Jaros, et al. v. Pfizer, Inc., et al.</u>, No. 116110/04 (Sup. Ct. New York County filed Nov. 15, 2004) (dismissing Plaintiffs' § 349 claim against Pfizer Defendants in nearly identical case) (internal citations omitted). The Complaint further fails to plead causation because it does not allege that Plaintiffs saw any such statement before they were prescribed Celebrex or Bextra. Accordingly, the Section 349 claim should be dismissed as inadequately pled.

CONCLUSION

For the reasons stated herein, Pfizer Defendants respectfully request that their Motion to

Dismiss be granted.

Dated: New York, New York

July 20, 2005

By:

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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK

IN RE: NEW YORK BEXTRA AND CELEBREX PRODUCT LIABILITY LITIGATION

Index No. 762000/06

Index No. 106237/05

TIPULATION OF

HELEN BILIK, ELIZABETH BOONE, MARY MAHAR, CAROLYN S. CROFT, GERALDINE M ALAPECK, DEAN SANTACROSE, AND STAMA SIMMONS,

No Later

A FOR against-

PARTIAL DISMISS
WITH PREJUDICE
AGAINST PFIZER
and PHARMA & DEFENDANTS

PFIZER INC., PHARMACIA CORPORATION, a was owned subsidiary of PFIZER INC., and PHARMACIA & & UPJOHN COMPANY, a wholly-owned subsidial of PHARMACIA CORPORATION, and MERCK & CO., INC.,

Defendants.

IT IS HEREBY STIPULATED AND AGREED, by and between Plaintiff-Helen Bilik("Plaintiff"), Defendants Pfizer Inc., Pharmacia Corporation and Pharmacia & Upjohn Company
("Pfizer Defendants") and Defendant Merck & Co., Inc. through their respective attorneys, that
whereas no party hereto is an infant, incompetent person for whom a committee has been
appointed or conservatee and no person not a party has an interest in the subject matter of this
action, Plaintiff Helen Bilik's claims asserted against Pfizer Defendants, which were filed in a
multi-plaintiff Complaint against Pfizer Defendants and Merck & Co., Inc., are dismissed with
prejudice.

This Stipulation, however, is a partial dismissal in that it does not affect any claims, counterclaims or issues by and between Defendants and Plaintiffs Elizabeth Boone, Mary J. Mahar, Carolyn S. Croft, Geraldine M. Alapeck, Dean Santaerose, or Stasia Simmons. This

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Stipulation may be filed without further notice with the Clerk of the Court. A facsimile copy of this Stipulation shall have the same effect as the original.

Dated: New York, New York
March 5 2008

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Filed 04/18/2008

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Dated: New York, New York

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